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EXECUTIVE COMMITTEE OF
THE MULTILATERAL FUND FOR THE
IMPLEMENTATION OF THE MONTREAL PROTOCOL
Fifty-fifth Meeting
Bangkok, 14-18 July 2008

UNIDO'S WORK PROGRAMME AMENDMENTS FOR 2008

COMMENTS AND RECOMMENDATION OF THE FUND SECRETARIAT

1. UNIDO is requesting approval from the Executive Committee for US $12,495,760 for its 2008 Work Programme Amendment, plus agency support costs of US $938,682.

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

Table 1: UNIDO's Work Programme Amendment

Country	Activity/Project	Amount Requested (US $)	Amount Recommended (US $)
SECTION A: ACTIVITIES RECOMMENDED FOR BLANKET APPROVAL			
A1. Institutional strengthening project:			
Montenegro	Institutional strengthening (phase I, years 1 and 2)	60,000	60,000
	Subtotal for institutional strengthening:	60,000	60,000
A2. Project preparation for MB:			
Colombia	Methyl bromide assistance	40,000	40,000
	Subtotal for project preparation for MB:	40,000	40,000
SECTION B: ACTIVITIES RECOMMENDED FOR INDIVIDUAL CONSIDERATION			
B1. Project preparation for HCFC investment projects:			
Albania	Project preparation for HCFC phase-out management plan	244,650	
Algeria	Project preparation for HCFC phase-out management plan	392,000	
Argentina	Project preparation for HCFC phase-out management plan	214,500	
Bahrain	Project preparation for HCFC phase-out management plan	61,000	
Bosnia and Herzegovina	Project preparation for HCFC phase-out management plan	244,650	
Cameroon	Project preparation for HCFC phase-out management plan	244,650	
China	Project preparation for HCFC phase-out management plan	580,250	
Croatia	Project preparation for HCFC phase-out management plan	244,650	
Egypt	Project preparation for HCFC phase-out management plan	643,500	
Eritrea	Project preparation for HCFC phase-out management plan	244,650	
Honduras	Project preparation for HCFC phase-out management plan	122,326	
India	Project preparation for HCFC phase-out management plan	214,500	
Indonesia	Project preparation for HCFC phase-out management plan	214,500	
Islamic Republic of Iran	Project preparation for HCFC phase-out management plan	196,000	
Iraq	Project preparation for HCFC phase-out management plan	299,302	
Jordan	Project preparation for HCFC phase-out management plan	244,650	
Kenya	Project preparation for HCFC phase-out management plan	122,326	
Korea, DPR	Project preparation for HCFC phase-out management plan	122,326	
Kuwait	Project preparation for HCFC phase-out management plan	122,326	
Libyan Arab Jamahiriya	Project preparation for HCFC phase-out management plan	392,000	
Macedonia, FYR	Project preparation for HCFC phase-out management plan	244,650	
Madagascar	Project preparation for HCFC phase-out management plan	122,326	
Malaysia	Project preparation for HCFC phase-out management plan	196,000	
Mexico	Project preparation for HCFC phase-out management plan	321,750	
Moldova	Project preparation for HCFC phase-out management plan	122,326	
Montenegro	Project preparation for HCFC phase-out management plan	244,650	

Morocco	Project preparation for HCFC phase-out management plan	244,650	
Nicaragua	Project preparation for HCFC phase-out management plan	244,650	
Niger	Project preparation for HCFC phase-out management plan	122,326	
Nigeria	Project preparation for HCFC phase-out management plan	196,000	
Oman	Project preparation for HCFC phase-out management plan	190,000	
Pakistan	Project preparation for HCFC phase-out management plan	321,750	
Qatar	Project preparation for HCFC phase-out management plan	127,500	
Saudi Arabia	Project preparation for HCFC phase-out management plan	547,000	
Senegal	Project preparation for HCFC phase-out management plan	244,650	
Serbia	Project preparation for HCFC phase-out management plan	244,650	
South Africa	Project preparation for HCFC phase-out management plan	643,500	
Sudan	Project preparation for HCFC phase-out management plan	392,000	
Syrian Arab Republic	Project preparation for HCFC phase-out management plan	392,000	
Tunisia	Project preparation for HCFC phase-out management plan	244,650	
Turkey	Project preparation for HCFC phase-out management plan	643,500	
Turkmenistan	Project preparation for HCFC phase-out management plan	244,650	
Venezuela, Bolivarian Republic of	Project preparation for HCFC phase-out management plan	643,500	
Yemen	Project preparation for HCFC phase-out management plan	122,326	
	Subtotal for project preparation for HCFC investment projects:	12,225,760	*
B2. Project preparation for MDI:			
Algeria	MDI project preparation	30,000	
Syrian Arab Republic	MDI project preparation	40,000	
Venezuela, Bolivarian Republic of	MDI project preparation	40,000	
	Subtotal for project preparation for MDI:	110,000	*
B3. MDI strategies:			
Korea, DPR	MDI transitional strategy	30,000	
Mongolia	MDI transitional strategy	30,000	
	Subtotal for MDI strategies:	60,000	*
Subtotal for sections A and B:		12,495,760	100,000
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):		938,682	8,100
Total:		13,434,442	108,100

* Projects for individual consideration or pending

SECTION A: ACTIVITY RECOMMENDED FOR BLANKET APPROVAL

A1. Renewal of institutional strengthening project:

Montenegro (Phase I, years 1 and 2): (US $60,000)

Project description

3. UNIDO submitted a request for Phase I of the institutional strengthening project in Montenegro. The description of the institutional strengthening project for the above country is presented in Annex I to this document.

Fund Secretariat's comments and recommendation

4. Montenegro has so far received funds only for the start up of their institutional strengthening project at the 51st Meeting. This request is submitted for the first full phase of an IS project with funding provided until the end of 2010. The ODS consumption of Montenegro for 2006 is 15.4 ODP tonnes. It is considered a low-volume-consuming-country therefore its IS funding will be in line with decision 35/57.

5. The Fund Secretariat recommends blanket approval of the institutional strengthening Phase I request for Montenegro at the level of funding shown in Table 1. The Executive Committee may wish to express to the Government of Montenegro the comments which appear below:

> The Executive Committee has reviewed the report presented with the institutional strengthening project renewal request for Montenegro and notes with appreciation that Montenegro reported data to the Ozone Secretariat as at end 2007, which was considerably lower than its average CFC compliance baseline. While Montenegro does no longer need CFCs in the production sector, those will still be required in the servicing sector until completion of the chillers replacement project. The Executive Committee also notes that within the framework of the institutional strengthening project, Montenegro has taken significant steps to phase out its ODS consumption; specifically, preparation of the country programme and terminal phase-out management plan, introduction and implementation of legislative and administrative measures, issuance of import/export permits and establishing quota system, banning of import of second-hand products in big quantities, initial activities for the identification of HCFC through an awareness workshop. In the framework of the UNEP CAP programme, public awareness workshops took place with importers/exporters, service providers, customs, statistics, representatives of vocational schools and environmental inspectors. Montenegro is an active member of the Regional Ozone Network for Europe and Central Asia. The Executive Committee greatly supports the efforts of Montenegro to reduce the consumption of CFCs. The Executive Committee is therefore hopeful that, in the next two years, Montenegro will continue with the implementation of its country programme and the TPMP activities with outstanding success in the further reduction of current CFC consumption levels.

A2. Project preparation for MB

Colombia: Methyl bromide assistance (US $40,000)

Project Description

6. On behalf of the Government of Colombia, UNIDO is submitting a request for a technical assistance project for methyl bromide. Colombia has a baseline consumption of methyl bromide of 110 ODP tonnes. From 1997, it has consistently reported zero methyl bromide consumption.

7. The project aims to maintain this zero consumption by providing information on the availability of viable alternatives to new growers that may start using methyl bromide. This technical assistance will also aim to establish and strengthen existing legal mechanisms and regulations to avoid the diversion of methyl bromide from its use for quarantine and pre-shipment to controlled uses in agriculture.

Fund Secretariat's comments

8. The Secretariat notes that Colombia is one of the major growers and exporters of cut flowers, an industry that uses methyl bromide. Due to innovative practices, the country has not used methyl bromide in this important application. However, the country has indicated that there is an expansion of the flower growing areas and the whole horticulture industry is growing, therefore there is a possibility that if left unchecked there would be a potential for pressure from these new growers to import methyl bromide for cut flowers.

9. In discussing this project with UNIDO, the Secretariat was informed that the Government is aware of the potential for new MB uses to emerge, and is seeking assistance in order to prevent this. The proposed activities include holding three workshops in the general areas where flower production is increasing, and to initiate the development of a legal mechanism that will strictly limit the use of MB to QPS uses only with strong sanctions on those who attempt to divert MB to controlled uses. The Government also intends to implement a system for strict monitoring from an import level which may include labelling to identify MB for QPS uses.

10. Colombia has received funding for a demonstration project for alternatives to the use of MB for bananas at the 26th Meeting. In submitting this request, the Government of Colombia agrees that this will be the final funding for methyl bromide phase-out for the country, and that it will not seek any future assistance for the same substance.

Fund Secretariat's recommendations

11. The Fund Secretariat recommends blanket approval for this project at the level of funding indicated in Table 1 above as the final funding for methyl bromide phase-out in Colombia.

SECTION B: ACTIVITIES RECOMMENDED FOR INDIVIDUAL CONSIDERATION

B1. Project preparation for HCFC investment projects

	Country	Project	Amount requested (US $)
(a)	Albania	Project preparation for HCFC phase-out management plan	244,650
(b)	Algeria	Project preparation for HCFC phase-out management plan	392,000
(c)	Argentina	Project preparation for HCFC phase-out management plan	214,500
(e)	Bahrain	Project preparation for HCFC phase-out management plan	61,000
(f)	Bosnia and Herzegovina	Project preparation for HCFC phase-out management plan	244,650

(g)	Cameroon	Project preparation for HCFC phase-out management plan	244,650
(h)	China	Project preparation for HCFC phase-out management plan	580,250
(i)	Croatia	Project preparation for HCFC phase-out management plan	244,650
(j)	Egypt	Project preparation for HCFC phase-out management plan	643,500
(k)	Eritrea	Project preparation for HCFC phase-out management plan	244,650
(l)	Honduras	Project preparation for HCFC phase-out management plan	122,326
(m)	India	Project preparation for HCFC phase-out management plan	214,500
(n)	Indonesia	Project preparation for HCFC phase-out management plan	214,500
(o)	Islamic Republic of Iran	Project preparation for HCFC phase-out management plan	196,000
(p)	Iraq	Project preparation for HCFC phase-out management plan	299,302
(q)	Jordan	Project preparation for HCFC phase-out management plan	244,650
(r)	Kenya	Project preparation for HCFC phase-out management plan	122,326
(s)	Korea, DPR	Project preparation for HCFC phase-out management plan	122,326
(t)	Kuwait	Project preparation for HCFC phase-out management plan	122,326
(u)	Libyan Arab Jamahiriya	Project preparation for HCFC phase-out management plan	392,000
(v)	Macedonia, FYR	Project preparation for HCFC phase-out management plan	244,650
(w)	Madagascar	Project preparation for HCFC phase-out management plan	122,326
(x)	Malaysia	Project preparation for HCFC phase-out management plan	196,000
(y)	Mexico	Project preparation for HCFC phase-out management plan	321,750
(z)	Moldova	Project preparation for HCFC phase-out management plan	122,326
(aa)	Montenegro	Project preparation for HCFC phase-out management plan	244,650
(bb)	Morocco	Project preparation for HCFC phase-out management plan	244,650
(cc)	Nicaragua	Project preparation for HCFC phase-out management plan	244,650
(dd)	Niger	Project preparation for HCFC phase-out management plan	122,326
(ee)	Nigeria	Project preparation for HCFC phase-out management plan	196,000
(ff)	Oman	Project preparation for HCFC phase-out management plan	190,000
(gg)	Pakistan	Project preparation for HCFC phase-out management plan	321,750
(hh)	Qatar	Project preparation for HCFC phase-out management plan	127,500
(ii)	Saudi Arabia	Project preparation for HCFC phase-out management plan	547,000
(jj)	Senegal	Project preparation for HCFC phase-out management plan	244,650
(kk)	Serbia	Project preparation for HCFC phase-out management plan	244,650
(ll)	South Africa	Project preparation for HCFC phase-out management plan	643,500
(mm)	Sudan	Project preparation for HCFC phase-out management plan	392,000
(nn)	Syrian Arab Republic	Project preparation for HCFC phase-out management plan	392,000
(oo)	Tunisia	Project preparation for HCFC phase-out management plan	244,650
(pp)	Turkey	Project preparation for HCFC phase-out management plan	643,500
(qq)	Turkmenistan	Project preparation for HCFC phase-out management plan	244,650
(rr)	Venezuela, Bolivarian Republic of	Project preparation for HCFC phase-out management plan	643,500
(ss)	Yemen	Project preparation for HCFC phase-out management plan	122,326

Project descriptions

12. UNIDO submitted a total of 44 requests for the preparation of HPMPs to this meeting, broken down as follows:

UNIDO's requests	Number of requests
UNIDO only	20
UNIDO/UNEP	15
UNIDO/UNDP	4
UNIDO and at least two other agencies	5
Total	44

13. In its submission, UNIDO provided a table that showed a breakdown of the elements of the HPMP preparation request as well as the costs associated with each. From the table, it can be seen that UNIDO used the LVC classification to determine costs for the country, but did not provide any information on the HCFC consumption of the countries for which funding was being sought.

14. UNIDO's cost request was broken down as follows:

UNIDO's requests	Total Costs in US $
For LVC countries	244,600
For medium consumers	392,000
For large consumers	643,500

15. The corresponding activities and their costs are listed in the table below:

Component	LVC Total cost	Medium Total cost	Large Total cost
1. Kick-off stakeholder workshop			
Sub-Total	24,500	47,500	94,250
2. Policy/legislative/regulatory and institutional framework			
Sub-Total	26,250	37,500	48,750
3. Data collection and surveys (Consumption Sector)			
Sub-Total	50,750	69,000	110,750
4. Strategy and plan for the implementation of HCFC phase out			
Sub-Total	59,500	104,500	179,500
5. Cost calculation			
Sub-Total	10,500	21,000	31,500
6. Project coordination and management			
Sub-Total	48,600	65,000	84,500
7. HPMP Finalization Workshop			
Sub-Total	24,500	47,500	94,250
Total	244,600	392,000	643,500

* This cost estimate does not consider additional costs for the production sector
**In countries where 2 or more agencies are cooperating, these costs were split with the other agencies considering the sectors on which each agency will be working and the role that it is playing (lead or cooperating).

Fund Secretariat's comments

16. In the absence of agreed funding policies specifically related to HCFCs, the Secretariat drew on the Fund's experience to date of addressing ODS phase out. In reviewing these requests the Secretariat considered the following:

(a) Latest HCFC consumption in the countries on the list based on Article 7 data;

(b) Common elements of HPMP project preparation as seen from the submissions;

(c) HPMP guidelines as approved in decision 54/39, and the elements of an HPMP as indicated therein;

(d) Earlier costs of country programme preparation, RMP/TPMP/NPP preparation as well as costs for the preparation of sector plans for CFC phase out for all countries as well as costs for individual preparation for countries with HCFC manufacturing; and

(e) Costs of earlier approved HCFC surveys for 13 countries.

17. In line with decision 54/39, the Secretariat also classified the countries into two main categories:

(a) Countries with HCFC consumption in the servicing sector only (HCFC-22); and

(b) Countries with HCFC consumption in both servicing and manufacturing (HCFC-22, HCFC-141b and other HCFCs).

18. To determine standard costs in line with previous decisions and guidelines of the Executive Committee, the Secretariat has concluded that HPMP preparation funding could be divided into the following components, in line with decision 54/39:

(a) Assistance for policy and legislation;

(b) Survey of HCFC use and analysis of data;

(c) Development and finalization of the full HPMP including consultations; and

(d) Individual investment project proposals.

19. The Secretariat also considered that all the first three components indicated in paragraph 18 above would be common to all countries regardless of consumption. The last component will apply only to those countries that have HCFC use in manufacturing. In considering the first three components the Secretariat also notes that, for some countries, these may already include some elements of small investment projects that may be up for simple conversions and where the alternative is already known.

20. UNIDO has indicated that they are lead in 20 countries out of the 44 submitted. The agency provided a list of tasks covering its responsibilities as lead agency, as well as a justification for the costs it has submitted, and these are attached to this document.

21. The Secretariat noted that for those countries where multiple agencies are working, there seems to be a lack of coordination on the specific role each agency will play, and the role of the lead agency is not very clear. UNIDO informed the Secretariat that for those countries where they are lead, they have had discussions with the other cooperating agencies and are confident that the costs have been divided equitably between those concerned. UNIDO also stressed that, as lead agency, it will make sure that no overlap of activities happens in these countries between the agencies.

22. In the case of China, the total request for HPMP preparation submitted for China by all agencies is US $4,532,995, of which the UNIDO component cost is over US $580,000. UNIDO justifies this request as being that agreed with the Chinese government vis-à-vis the responsibilities of the other agencies by sector, and this will cover project preparation for investment projects for the domestic refrigeration sector. In responding to the Secretariat's requests for details on this specific funding level (i.e. how many individual projects, what approach will be taken), UNIDO did not provide this to the Secretariat as of the writing of this document.

23. UNIDO provided the Secretariat with a detailed budget breakdown for the categories of countries where funding is being sought. This breakdown proposes specific activities with their corresponding costs. In discussions with UNIDO, the Secretariat requested UNIDO to further review these costs, and to resubmit having considered the approach and cost proposals by the Secretariat. After a number of discussions, there was no agreement with UNIDO on the proposed costs for the countries, including that for China. In view of the complexity and size, the Secretariat believes that China would need to be considered separately from the other HPMP preparation funding requests.

24. In view of the wide range of costs submitted by the agencies for the HPMP preparation funding requests, the Secretariat, following a detailed analysis as mentioned above, proposed the following costs, summarized in the table below:

Summary table of recommended costs for HPMP preparation

Country classification	zero consumption	countries with servicing only (HCFC-22 only)	countries with servicing and manufacturing* (mid-consumption countries)	countries with servicing and manufacturing* (larger consumption countries)
ACTIVITY	**BUDGETS (US$)**			
1. Policy assistance for HCFC licensing system				
Legal consultant(s)	4,000	10,000	15,000	15,000
Consultation meetings to finalise guidelines and rules	4,000	5,000	10,000	10,000
Information Dissemination for enforcement	2,000	5,000	5,000	5,000
Sub-total:	**10,000**	**20,000**	**30,000**	**30,000**
2. Survey, Data collection and Analysis**				
Consultant costs	5,000	10,000	20,000	40,000
Stakeholder consultation meeting and finalisation of report	5,000	5,000	10,000	10,000
Data collection costs (including travel, if required)	5,000	10,000	25,000	35,000
Sub-total:	**15,000**	**25,000**	**55,000**	**85,000**
3. Strategy development and finalisation				
3 national meetings (start of the process, initial consultation and final consultation)	10,000	15,000	20,000	30,000
Documentation and information materials (sub-contract)	5,000	5,000	5,000	5,000
local travel expenses for meeting participants	10,000	20,000	15,000	15,000
Consultants to review technology including climate benefits	Not applicable	Not applicable	25,000	30,000
Sub-total:	**25,000**	**40,000**	**65,000**	**80,000**
Total Cost	**50,000**	**85,000**	**150,000**	**195,000**

* these costs are standard costs for the preparation of the HPMP, individual project preparation for demonstration and other investment projects will be costed separately

** funding already received by countries for surveys will be adjusted lower than these proposed costs, accordingly.

25. The Secretariat discussed with the agency the level of funding submitted for project preparation of the HPMPs for the countries listed in its work programme amendment. Although there appeared to be agreement on the approach being proposed for by the time of writing this document, no agreement on cost has been reached.

Fund Secretariat's recommendation

26. Pending.

B2. Project preparation for CFC-MDI Conversion projects

Background

27. 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."

Algeria: MDI project preparation (US $30,000)

Project description

28. On behalf of the Government of Algeria, UNIDO is submitting a request for the preparation of an MDI conversion project including an MDI-transition strategy to phase-out CFC use in the MDI production and consumption sectors. The cost as originally submitted is US $50,000. The project will phase out 5.9 ODP tonnes in the CFC MDI sector.

29. At the 53rd Meeting, the Executive Committee approved the national ODS Phase-out Plan for Algeria at a funding level of US$ 921,500. The project included training, technical assistance and investment activities and addressed all the remaining consumption of CFCs. The ODS consumption in the MDI sector, which was 5.96 MT of CFCs in 2006, was not addressed at that time due to the small volume of CFCs used in MDI production. Another reason cited was that responsibility for MDIs and the whole pharmaceutical sector was controlled by the Ministry of Health while the Government authority directly responsible for the Montreal Protocol was the Ministry of Environment.

30. In support of its submission for project preparation funds, and in response to decision 51/34, UNIDO indicated that as of 2006 the Government of Algeria has one CFC-MDI manufacturing enterprise, the Algerian Pharmaceutical Laboratory (LPA), a company which is 100 percent nationally owned. While the company was founded in 1991, the MDI line for the

production of salbutamol was installed only in 2005 under licence from Chiesi Italy, with full production commencing in 2006.

31. LPA has one production line with a production capacity of 5 million units annually. The company produces only one product, salbutamol, and its production is for domestic consumption only. Since it commenced production only in 2006, the data below provides the information on annual production and CFC use only for the years 2006 and 2007.

Year	Number of Units	CFC used (MT)	
		CFC-11	CFC-12
2006	333,000	1.7	2.4
2007	480,000	4.3	6.2

32. The project data indicates that the company contemplates a shift to HFA alternatives, and the current production line will have to be entirely replaced as it cannot be retrofitted.

33. Algeria imports both CFC and non-CFC-MDIs. In 2007, total imports were about 3.8 million units. The country imports higher quantities of CFC-free MDIs in comparison with CFC MDIs. Small quantities of DPIs are also available on the market, although these are too expensive for the majority of the Algerian population. The details of the imports into Algeria are attached as part of UNIDO's work programme amendment submission.

Fund Secretariat's comments

34. The project preparation request is being submitted to enable the phase-out of 5.96 ODP tonnes of CFCs used in the manufacture of CFC-MDIs. The Secretariat notes that while the proposal mentions that the NPP which was approved in 2007, did not include the MDI production since it was negligible. However, at the time of the submission of the NPP, the document indicated that most of the needs for CFC-MDIs in the country were met through imports, and that Algeria did not possess facilities for MDI production. UNIDO clarified that when the NPP was prepared in 2006, the production of MDIs was not included as LPA started producing only in that year. The Secretariat also noted that in the report of its country programme implementation for 2007, Algeria did not indicate any CFC use for MDIs. Data for compliance also show that Algeria has remaining funding eligibility of zero ODP tonnes following the compliance oriented model.

35. In reviewing the data submitted for the single company under consideration, the Secretariat noted that MDI production has increased from 2006-2007, as shown by the number of units produced. UNIDO informed the Secretariat that the production from LPA is only for domestic consumption as it imports more than it produces. UNIDO also advised that the incidence of COPD in the country is on the rise, and is becoming an important public health problem. It is to be noted, however, that the annual production of less than 300,000 MDIs is less than 8 percent of the total MDIs imported into the country.

36. While UNIDO provided information on the imports of CFC-MDIs into the country as required in decision 51/34, this did not include information on the price of the products.

37. In discussing the company's plans for conversion, the Secretariat was advised that the company is looking into converting its production facilities to HFA, and that the possibility of co-financing has been discussed.

38. The Secretariat and UNIDO discussed the funding being requested for this project preparation. UNIDO agreed to adjust the funding request to US $30,000 from the US $50,000 originally requested.

Fund Secretariat's recommendation

39. In the light of the comments above, the Executive Committee may wish to consider approval of the request for MDI project preparation for Algeria 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.

40. In approving this project UNIDO 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.

Syrian Arab Republic: MDI project preparation (US $40,000)

Project description

41. On behalf of the Government of Syria, UNIDO is submitting a request for project preparation to phase-out CFC use in the MDI manufacturing sector. The project will phase out some 50 ODP tonnes of CFCs used in this sector.

42. The CFC National Phase-out Plan for Syria was approved by the Executive Committee at its 49th ExCom Meeting in 2006 at the funding level of US $745,050. It addressed all the remaining consumption of CFCs, which was 869.7 ODP tonnes as of 2005. The project included training, technical assistance and investment activities. The ODS consumption of 25.71 metric tonnes in the MDI sector for 2005 was not covered in this project because the NOU was not informed about the CFC consumption in the MDI production at Kaspar-Chabani Pharma (also known as K.C. Pharma), which is under the control of the Ministry of Health.

43. In support of its submission for project preparation funds and in response to decision 51/34, UNIDO indicated that as of 1998 the Government of Syria has one CFC-MDI manufacturing enterprise, K.C. Pharma which is 100 percent nationally owned. While the company was founded in 1998, its first MDI production was only in 1999.

44. The submitted documentation shows that the company produces seven products, and the current CFC-MDI production equipment capacity is 3600 cans/hour, and about 8.5 million cans/year on a single production line, single shift per day. However, the actual MDI demand met by KC Pharma in Syria in 2007 was around 2.0 million MDIs per year. These products are being produced under license from Chiesi, Italy.

45. The table below provides production data for the last five years for each of their products:

Product	Composition	2003	2004	2005	2006	2007
Butovent Spray	Salbutamol BP 100 mcg/puff	634,000	697,000	780,400	874,000	1,235,000
Clenil Forte Spray	Beclomethasone Dipropionate 250 mcg/puff	61,000	67,000	75,000	84,000	99,300
Clenil Spray	Beclomethasone Dipropionate 50 mcg/puff	83,000	90,900	101,800	114,000	141,000
Clenil Forte jet	Beclomethasone Dipropionate 250 mcg/puff	3,700	4,100	4,600	5,100	-
Clenil Compositum Spray	Beclomethasone Dipropionate 50 mcg/puff Salbutamol BP 100 mcg/puff	59,050	65,000	72,800	81,500	104,700
Asthmatide 50	Salmeterol 25 mcg/puff Fluticasone Propionate 50 mcg/puff		4,100	8,200	6,400	12,400
Asthmatide 125	Salmeterol 25 mcg/puff Fluticasone Propionate 125 mcg/puff		11,600	25,400	32,600	49,900
Asthmatide 250	Salmeterol 25 mcg/puff Fluticasone Propionate 250 mcg/puff		7,400	16,900	23,800	36,200
Flusone 44	Fluticasone Propionate 50 mcg/puff	6,100	4,700	5,500	7,100	9,500
Flusone 110	Fluticasone Propionate 125 mcg/puff	7,500	11,700	7,600	14,200	16,800
Flusone 220	Fluticasone Propionate 250 mcg/puff	4,900	7,500	6,800	10,800	12,700
Asthmerol	Salmeterol 25 mcg/puff	14,600	32,500	37,800	39,100	46,200
Total		**873,850**	**1,003,500**	**1,142,800**	**1,292,600**	**1,763,700**

46. The project data indicates that the company contemplates a shift to HFA alternatives, and the current production line will have to be entirely replaced as it cannot be retrofitted.

47. Only two types of inhalers (salmeterol fluticasone and salbutamol) are allowed to be imported into Syria, and these are DPI based. In 2007, a total of 3,500 units of these two products were imported into the country. Syria did not provide data on imports of MDIs other than for the two already mentioned. The document states that other imports are prohibited, although it is believed there could be illegal importation of CFC MDIs and other CFC-MDIs into the country.

Fund Secretariat's comments

48. The project preparation request is being submitted to enable the phase-out of 51.7 ODP tonnes of CFCs used in the manufacture of CFC-MDIs in Syria. The Secretariat noted that while the proposal mentions that the NPP, which was approved in 2006, it did not include the MDI production since it was not identified at the time of the project preparation due different responsibilities (i.e. the pharmaceutical sector is under the Ministry of Health). The Secretariat also noted that in the report of its country programme implementation submitted for 2007, Syria reported a consumption of 51.7 ODP tonnes in the MDI sector. In line with the compliance oriented model, data shows that Syria's remaining funding eligibility is zero ODP tonnes.

49. In reviewing the data submitted for the company under consideration, the Secretariat noted that production has almost doubled from 2003 to 2007 as shown in the table above. UNIDO informed the Secretariat that around 5-6 percent of the population use MDIs for asthma in the country. The company also used to export its products to Iraq, however recent regulations only allow HFA MDIs into the country so this has stopped. There is no indication of a number or of the volume of exports from the data provided.

50. UNIDO did not provide data on the trend of CFC use for the five years required under decision 51/34 for the company. It did indicate that, in 2007, there was an import of around 50 ODP tonnes of CFCs for the production of MDIs. The Secretariat was informed that the data was difficult to get since it went through the Ministry of Health and was considered a pharmaceutical ingredient, and therefore customs clearance was also done through this Ministry. UNIDO also advised that the company is presently obtaining the license and registration to commence production of budenoside CFC based MDIs.

51. In discussing the company's plans for conversion, the Secretariat was told that the company is looking into converting their production facilities to HFA, and that the possibility of co-financing has been discussed. In clarifying the two-year completion of the process, UNIDO responded that this period was foreseen only for the two most important MDIs: salbutamol and beclomethasone. The other formulations can be done between 6-12 months from project approval since work has already commenced on their conversion. UNIDO also indicated that, if approved, the company is willing to consider co-financing part of the conversion costs.

Fund Secretariat's recommendation

52. In the light of the comments above, the Secretariat's review shows that the documentation provided does not meet the full requirements of decision 51/34 and is unable to recommend this project for funding by the Executive Committee. The Executive Committee may wish to consider this request for MDI project preparation for the Syrian Arab Republic in light of the above comments.

Venezuela, Bolivarian Republic of: MDI project preparation (US $40,000)

Project description

53. On behalf of the Government of Venezuela, UNIDO is submitting a request for the preparation of an MDI conversion project, including an MDI-transition strategy, to phase-out CFC use in the MDI production and consumption sectors. The cost as originally submitted is US $50,000. The project will phase out 29.6 ODP tonnes of CFCs in the MDI sector.

54. At the 42nd Meeting, the Executive Committee approved the national CFC Phase-out Plan for Venezuela to phase out 2,032 ODP tonnes of CFCs in the country. UNIDO indicates that the 20 ODP tonnes or more of CFC consumption in the MDI sector was not properly addressed in the NPP, because the consumption was not correctly recorded, therefore the request for this funding.

55. In support of its submission for project preparation funds and in response to decision 51/34, UNIDO indicated that as of 1991 the Government of Venezuela has one CFC-MDI manufacturing enterprise, Laboratoris L.O. Oftalmi, CA., company which is 100 percent nationally owned. The company started MDI production in 1991, and supplies 80 percent of the requirement of the national health service. The rest of the 20 percent goes into the country's free market. The company does not export CFC-MDIs.

56. The actual production of Oftalmi is about 2 million units per day on the basis of an eight-hour working shift per day. Since there is no information on the number of production lines, it is assumed that this information is for one line only. The company produces four products, and the data on their production is summarized in the table below:

Product	2003	2004	2005	2006	2007
Venticort	261,086	363,514	368,640	463,112	785,419
Duovent (*)	63,220	66,910	45,315	0	0
Cromospray (*)	55,949	58,425	8,014	0	0
Salbutamol	596,111	593,054	732,649	555,787	546,296
Beclomax	294,378	325,415	319,616	141,663	423,680
Budecort	281,563	286,112	273,487	147,106	193,622
Total	**1,552,307**	**1,693,430**	**1,747,721**	**1,307,668**	**1,949,017**

(*) These products were discontinued in May 2004

57. The trend of CFC consumption is as follows:

Year	CFC-11	CFC-12	Total consumption of CFCs (in kg)
2003	8,450	12,266	20,716
2004	9,904	15,055	24,959
2005	11,714	16,391	28,105
2006	8,989	13,864	22,853
2007	12,106	17,454	29,560
Total	**51,163**	**75,030**	**126,193**

58. The project data indicates that the company contemplates a shift to HFA alternatives, and the current production line will have to be entirely replaced as it cannot be retrofitted.

59. Venezuela imports both CFC and non-CFC-MDIs. The document states that CFC-MDIs still dominate the import market. UNIDO provided import data only for the last three years as summarized below, according to propellant used:

	2005	2006	2007
CFC MDIs	761,300	923,000	1,007,200
DPIs	369,700	470,200	561,400
HFA MDIs	592,700	771,300	854,000
Total	**1,723,700**	**2,164,500**	**2,422,600**

Fund Secretariat's comments

60. The project preparation request is being submitted to enable the phase-out of 29.6 ODP tonnes of CFCs used in the manufacture of CFC-MDIs. The Secretariat notes that while the proposal mentions that the NPP, which was approved in 2004, it did not include the amount of CFCs used for MDI production, as this consumption was apparently not identified during the project preparation and was therefore not addressed in the NPP. The Secretariat also noted that in the report of its country programme implementation for 2007, Venezuela reported a consumption of 29.6 ODP tonnes in the MDI sector. In line with the compliance oriented model, data shows that Venezuela's remaining funding eligibility is zero ODP tonnes.

61. In reviewing the data submitted for the company, the Secretariat noted that production has steadily increased. In particular, the production of salbutamol, which had been going up since 2003, seems to have decreased in 2006 and 2007. This may have been due to imports of this drug. UNIDO also advised the Secretariat that the company is a source of affordable MDIs that are provided for the larger part of the population with COPD.

62. In discussing the company's plans for conversion, the Secretariat inquired about licensing agreements and/or technical assistance contracts between Laboratorios L.O. Oftalmi, C.A. and any other pharmaceutical companies, particularly for the transfer of technology to effect the conversion. The Secretariat was informed that Oftalmi had expertise that will be able to look at these issues, as it is the only leading MDI manufacturer in the country. UNIDO also informed the Secretariat that the company is looking into converting its production facilities to HFA, and that the possibility of co-financing has been discussed with the company which is open to the

idea of sharing the costs for the conversion. UNIDO also reiterated that the final project will include a full national MDI transition strategy.

63. In discussing the cost of the project, the Secretariat requested UNIDO to revisit its costs as these were too high for the consumption. UNIDO agreed to reduce the project preparation funding request to US $40,000.

Fund Secretariat's recommendation

64. In the light of the comments above, the Secretariat's review shows that the documentation provided does not meet the full requirements of decision 51/34 and is unable to recommend this project for funding by the Executive Committee. The Executive Committee may wish to consider this request for MDI project preparation for Venezuela in light of the above comments.

B3. MDI strategies

Background

65. The Executive Committee, at its 51st Meeting, agreed in decision 51/34(d) *inter alia*, "to consider on a case-by-case basis requests for transition strategies to non-CFC MDIs in Article 5 Parties that did not have MDI manufacturing facilities, in accordance with decision 45/54, when the need for a strategy had been fully demonstrated and documented through the submission of the following information for the previous three years:

(a) CFC and non-CFC MDIs and dry-powder inhalers: sold or distributed within the Party, by active ingredient, brand/manufacturer, and source;

(b) Non-CFC MDIs and dry-powder inhalers: date approved, authorized for marketing, and/or launched in the territory of the Party;

(c) CFC and non-CFC MDIs and dry-powder inhalers: estimated cost by active ingredient and source."

Korea, DPR: MDI transitional strategy (US $30,000)

Project description

66. On behalf of the Government of the Democratic Republic of Korea (DPR Korea), UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector. Data provided with the submission show that DPR Korea does not manufacture CFC MDIs. It also showed that the trends for both CFC and non-CFC MDIs imports are increasing. The available data indicates that over 2 million units were imported in 2005 and 2007, but this has dropped to 1.9 million units in 2007. The main source of imports is Russia.

67. There is also an overall concern from the Government of DPR Korea and its health authorities about the MDI sub-sector, particularly since the statistics show that that there are over 900,000 incidences of chronic destructive pulmonary disease (COPD) and asthma in the country.

There would therefore appear to be an urgent need to ensure a steady supply of affordable MDIs to meet these patients' needs. The requested funding for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs. Since DPR Korea is a centrally planned economy and the national Government fully supports this request, it is envisaged that the transition strategy will be implemented as planned. It will include the drafting of regulations needed that would promote and support the phase-out of these products, and a programme that would raise physician awareness and patient acceptance of alternatives to CFC-MDIs, as well as monitoring imports of MDIs.

68. In support of its submission and based on decision 51/34, UNIDO indicated that the situation with regards to the supply of MDIs and their non-CFC equivalents in DPR Korea can be briefly described as follows:

(a) CFC MDIs are available but there are no non-CFC equivalents, either HFC products or powder inhalers;

(b) Imports of CFC MDIs decreased slightly from 2005-2007. 2,311,600 units were imported in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007; and

(c) Prices for the last three years have remained stable.

69. The table below summarises the imports of MDIs into DPR Korea for the last three years:

MDI brand name	Active ingredient	Cost of one MDI, US$	Propellant	MDI units imported/year		
				2005	2006	2007
Ventalex	Salbutamol	2	CFC	2,126,000	2,013,400	1,867,400
Beclex	Beclamethasone	2	CFC	185,600	200,040	196,650
			Total	2,313,600	2,213,440	2,064,050

Fund Secretariat's comments

70. The project preparation request is being submitted to enable the smooth transition to non-CFC MDIs in DPR Korea, therefore phasing out CFC consumption in the MDI sector. In reviewing the data and information submitted, the Secretariat noted that there are only two products that are imported into the country, namely salbutamol (over 90 per cent of the import) and beclomethasone. Both these products come from one source, the Russian Federation, and the alternatives, HFA-salbutamol and HFA- beclomethasone, are well developed and available world wide.

71. In view of the above, the Secretariat does not consider that the need for a CFC-MDI transition strategy for DPR Korea has been justified.

Fund Secretariat's recommendation

72. In the light of the comments above, Secretariat cannot recommend the funding requested for the development of a CFC-MDI transition strategy for DPR Korea.

Mongolia: MDI transitional strategy (US $30,000)

Project description

73. On behalf of the Government of Mongolia, UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector. Data provided with the submission show that Mongolia does not manufacture CFC MDIs, and that the country imports only one MDI product, salbutamol, from the Russian Federation.

74. There is also an overall concern from the Government of Mongolia and its health authorities about the MDI sub-sector, particularly since the statistics indicate that the incidences of chronic obstructive pulmonary disease (COPD) and asthma have increased in the country, therefore there is an urgent need to ensure a steady supply of affordable MDIs to meet these patients' needs. The requested funding for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs. Since Mongolia is a centrally planned economy and the national Government fully supports this request, it is envisaged that the transition strategy will be implemented as planned. It will include the drafting of regulations needed that would promote and support the phase-out of these products, and a programme that would raise physician awareness and patient acceptance of alternatives to CFC-MDIs, as well as monitoring imports of MDIs.

75. In support of its submission, and based on decision 51/34, UNIDO provided the following table to summarise the import of MDIs into Mongolia for the last three years:

Active ingredient	Manufacturer	Propellant	MDI units imported/year		
			2003	2004	2005
Salbutamol, aerosal-12ml	Moschimfarm, Russia	CFC		8,538	6,480
Salbutamol, aerosal-12ml	Altaivitamin, Russia	CFC	10,000		

Fund Secretariat's comments

76. The project preparation request is being submitted to enable the smooth transition to non-CFC MDIs in Mongolia, thereby phasing our CFCs. The proposal provides very limited information on the MDI sector. Imported data is only for 2003 to 2005 and none has been provided for 2006 and 2007. There is likewise no information on the date of approval by the local drug administration, as well as when marketing and launch in Mongolia was authorized.

77. Based on the information provided, the number of MDIs imported into the country is very small (less than 6,500 MDIs in 2005); salbutamol is the only active ingredient and all imports come only from the Russian Federation. It is noted that HFA-salbutamol is well developed and available world wide.

78. In further clarifying this request, UNIDO acknowledges that there is indeed very little information and data provided for Mongolia. They contend, however, that since even these small quantities of CFC MDIs need to be replaced with the HFA MDIs, an awareness programme is needed to educate doctors, pharmacists and patients. UNIDO stresses that the transition strategy could provide an analysis of the MDI market in Mongolia and assist in establishing a deadline for the entire CFC MDI phase out in the country. Efforts should be made jointly by the Ministry of Health, healthcare providers, physicians, pharmacists and nursing staff and all sectors linked to this. The strategy will also provide a document which will guide both medical practitioners as well as patients to understand the need for transition, as well as how this can be done smoothly, emphasising on the same quality of medication using the alternative.

79. The Secretariat, however, on the basis of the requirements of decision 51/34, does not consider that the need for a CFC-MDI transition strategy for Mongolia has been fully justified.

Fund Secretariat's recommendation

80. In the light of the comments above, the Secretariat cannot recommend the approval of the funding requested for the development of a CFC-MDI transition strategy for Mongolia.

Annex I

INSTITUTIONAL STRENGTHENING PROJECT PROPOSAL

Montenegro: Renewal of institutional strengthening

Summary of the project and country profile	
Implementing Agency:	UNIDO
Amounts previously approved for institutional strengthening (US $):	
IS start-up: Mar-2007	30,000
Total	30,000
Amount requested for renewal (Phase I – years 1 and 2) (US $):	60,000
Amount recommended for approval for Phase I (years 1 and 2) (US $):	60,000
Agency support costs (US $):	4,500
Total cost of institutional strengthening Phase I (years 1 and 2) to the Multilateral Fund (US $):	64,500
Equivalent amount of CFC phase-out due to institutional strengthening Phase I – years 1 and 2 at US $12.1/kg (ODP tonnes):	n/a
Date of approval of country programme:	Nov. 2007
ODS consumption reported in country programme (2006) (ODP tonnes):	14.1
Baseline consumption of controlled substances (ODP tonnes):	
(a) Annex A Group I (CFCs) (Average 1995-1997)	104.9
(b) Annex A Group II (Halons) (Average 1995-1997)	2.3
(c) Annex B Group II (Carbon tetrachloride) (Average 1998-2000)	1.1
(d) Annex B Group III (Methyl chloroform) (Average 1998-2000)	0
(e) Annex E (Methyl bromide) (Average 1995-1998)	0
Latest reported ODS consumption (2006) (ODP tonnes) as per Article 7:	
(a) Annex A Group I (CFCs)	14.0
(b) Annex A Group II (Halons)	0
(c) Annex B Group II (Carbon tetrachloride)	0.1
(d) Annex B Group III (Methyl chloroform)	0
(e) Annex E (Methyl bromide)	0
(f) Annex C Group I (HCFCs)	1.3
Total	15.4
Year of reported country programme implementation data:	2007
Amount approved for projects (US $):	245,000
Amount disbursed (as at May 2008) (US $):	19,973
ODS to be phased out (ODP tonnes):	3.0
ODS phased out (as at May 2008) (ODP tonnes):	-

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

	Summary of activities	**Funds approved (US $)**
(a)	Investment projects:	175,000
(b)	Institutional strengthening:	30,000
(c)	Project preparation, technical assistance, training and other non-investment projects:	40,000
	Total:	245,000

Progress report

2. The 51st Executive Committee approved funds for the start up of the institutional strengthening project to allow the country to set up the national ozone office and coordinate the activities for the CP/TPMP preparation. The National Ozone Unit is part of the Ministry of Tourism and Environment, and it is the focal point for Montreal Protocol activities. The NOU coordinates the implementation of the project objectives with the Minister of Tourism and Environment and with the legal service department in the same Ministry, who prepares proposals for legislation and submits it to the Government and Parliament for approval. The programme of activities related to the Montreal Protocol forms part of Montenegro's commitment to phasing out the consumption of ODSs in a controlled and cost-effective manner. Montenegro became party to the Montreal Protocol in 2006; the import/export licensing system was established as early as 2004, also the ban of import of second-hand products in big quantities, and since 2007 permits are issued in accordance with a quota system. A number of public awareness activities were carried out. The ozone officer also participated in technical meetings organized by UNEP and UNIDO. Montenegro has undertaken preliminary action towards the identification of HCFC and has reported HCFC data in its country programme report.

Plan of action

3. The NOU is seen as the nucleus of the ODS management structure and was established as a specialized body to provide the execution and follow-up of the ODS phase-out strategy as laid down in the action plan of the country programme. Regular access of the NOU to senior decision-makers is assured through a close collaboration with the Minister of Environment and with the legal service department in the same Ministry who prepares proposals for legislation and submits it to the Government and Parliament for approval. Montreal Protocol matters are part of the Ministry's yearly action plan and progress in the implementation of the Montreal Protocol is reported as part of the Ministry's report to the Government. Ozone issues will be part of the national integration plan of Montenegro with the European Union. The main objectives in the next years will be the implementation of the TPMP, the preparation of the HCFC survey and the HPMP, training of customs officers and an efficient recovery and recycling scheme.

Explanatory Note on the Costing of HPMP Preparatory Projects

1. The current HCFC consumption figures reported by the countries in previous years are in many cases misleading and inaccurate.
    a. On the basis of the level of development and size of industry of several countries and taking into consideration UNIDO's earlier experience working with them, we believe that some countries reported unrealistically high HCFC consumption data, whereas others reported very low.
    b. We also observed that in many countries HCFCs were phased in as alternatives to CFCs, however, some of these countries still report zero consumption of HCFCs.
    c. Countries, which reported zero consumption, would need more assistance in data reporting. We believe that such are still not ready yet to report reliable figures on HCFC consumption as having zero consumption in a country is practically not possible at the present time.
    d. The actual HCFC consumption data will be verified through the HPMP.
2. Since in many cases the currently available HCFC consumption data do not reflect the real consumption in the country they cannot be considered as the only basis for the calculation or categorization of countries at this point of time and it cannot be used as a reliable tool for determination of funding of the HPMP preparation.
3. When calculating funding requirements for HPMP preparation, costs for the preparation of individual investment projects should also be considered, since the 1st stage of the HPMP in countries with HCFC consumption in manufacturing sectors must include enterprise level investment projects as well.
4. The inflation during the last 15 years as well as the strong depreciation in the value of the US$ and the fast growing air fares should also be accounted for.
5. In addition, the geographical location, complexity and size of a country as well as its industrial structure are parameters that UNIDO considered in drawing the estimated figures.
6. It is also to be noted that in countries where we have dealt only with the servicing sector in the phase out of CFCs, it cannot be ruled out that HCFCs are being used in the manufacturing sector as well. So, for countries we see a likelihood of HCFC manufacturing uses we have to budget some funds in the preparation of the HPMP to avoid to the extent possible future additional requests for updates to accommodate the manufacturing sectors.
7. Requirements for the preparation of the HPMPs as per decision 54/39 are much more extensive than the requirements for the preparation of the CP/RMP/NPP or TPMP. Furthermore, TPMPs and NPPs in most cases dealt only with the 15% remaining consumption, at a time when we have already had clearer information about the situation of the different sectors in the Country. RMPs dealt with the refrigeration-servicing sub-sector only, while HPMP will have to review several sectors.
8. HCFC replacement technologies are not yet well established in Article 5 Countries, which creates an additional difficulty.
9. The stakeholders for HCFC phase-out are in many cases different from those, which were involved in the phase out of CFCs except for the second-stage conversion in the manufacturing sector. Thus, we never dealt with
    a. Enterprises established after 1995,
    b. Stakeholders in the sectors of air conditioning, part of commercial and industrial refrigeration sector, many XPS producers etc…
10. The task of the HPMP preparation is not limited to collection of additional data only but it also requires dealing with the selection of alternatives, technology transfer, priority setting, budgeting, strategy preparation, etc… According to the HPMP guidelines, the HPMP should include analysis and information about the availability of alternatives, selection of alternative technologies, ICC and IOC calculations, evaluation of climate change impact etc., as well as cost scenarios for the phase out. It is our understanding also that the HPMP should already include proposals for projects (investment and non-investment) to enable the Country's compliance with the 2013 and 2015 phase out control measures. The calculation of ICC and IOC for the manufacturing enterprises has to be enterprise specific especially in the initial stage. This needs to be budgeted – one time preparatory fund compensation for the sector is not sufficient as there is a need to design several enterprise level interventions. Without the said detailed information and justifications related to the investment projects difficulties will arise at the time of the review and approval process.

11. The HPMP will be a performance-based document while the CP was not. The reliability of the HPMP document should be far higher.
12. The regional network experts referred to by the Secretariat can be used in limited extent. There is a lack of knowledge and experience on alternatives to HCFCs in Article 5 Countries therefore international expertise will be required to work along with national experts who will have to prepare in-depth on site surveys, data collection etc. Costs for both expert categories should be accounted for.
13. According to the HPMP preparation guidelines, through the preparation and implementation of the HPMP, the agencies should *"Assisting the country in establishing a licensing system including a comprehensive monitoring and control system. Countries should be encouraged to include or revise their current licensing systems to accommodate the adjustments adopted at the XIVth Meeting of the Parties during the development of the overall HPMPs. As the funding for the full HPMP implementation is likely to be provided only subsequent to an update of current regulations to include HCFCs, the Executive Committee could require the availability of an appropriate licensing system for HCFCs to be in place as a condition for the approval of funding for HPMP implementation, consistent with current guidelines for TPMPs."* Therefore, we understand that even in cases where the licensing of HCFC is in place, the Countries are required to adjust that to the new phase out schedules, take policy measures to curb import of HCFC containing equipment and that the Agencies need to assist the countries in setting up a proper monitoring and control system. This is a very important aspect since it will be a condition for future funding related to the HPMP implementation.
14. According to our analysis and findings, the average level of PRP-funding approved by the Multilateral Fund in all countries in the various categories (considering the preparatory assistance funds approved for the preparation of projects in the foam, refrigeration and solvent sectors but excluding the halon, fumigation, aerosol and production sectors) was around US$ 350,000. The figure of US$ 100,000 quoted by the Secretariat is not a realistic one and cannot be used for the HPMP preparation considering the level of information to be collected and the current price and currency situation mentioned earlier. In addition, the funds approved for preparing individual projects should also be taken into account.
15. We would like to underline that the level of details required by the HPMP guidelines is much more elaborate than the data collected for the surveys approved earlier by the ExCom. In fact the surveys are only a part of one component of the overall plan.
16. UNIDO, when preparing its first submission evaluated the countries, based on their reported HCFC consumption and also based on their size, geographical location, industrial development and other parameters. All these factors determine the likely magnitude of resources needed to prepare the HPMP. So, the governing criteria have been the <u>expected real cost of preparation of the HPMP</u>. The smaller and simpler cases were put into the first category.
17. We did not calculate the cost of production closure projects. Maybe a separate category of countries with servicing, manufacturing and production needs should be considered.
18. In the Work Programme Amendment submitted earlier, UNIDO provided a detailed cost breakdown.
19. Based on our telephone conference we have reformulated our earlier submission with an attempt to follow the logic the Secretariat requested us to look at:
    a. We took into consideration the more detailed categorization of countries as presented by the Secretariat and classified our counterparts according to these categories.
    b. We have also grouped the activities in similar categories as recommended by the Secretariat; however an additional category of activities was added, which relates to coordination, management and monitoring of the HPMP preparation activities.
    c. We included average costing for each group of activities in each category of countries.
20. Following the approach directed by the Secretariat, we were able to reduce the total budget of our submission. The results are summarized in the two tables attached.

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	Cost	#	Cost	#	cost	#	cost	#	cost	#	cost
Policy	National expert (US$ 2,000/w.m.)	2,000	2	4,000	2	4,000	4	8,000	2	4,000	4	8,000	7	14,000	10	20,000
	International expert (US$ US$15,000/w.m.), incl. international travel	15,000	1.00	15,000	1.00	15,000	1	15,000	1.00	15,000	1	15,000	2.00	30,000	2	30,000
	Stakeholder consultation workshops (US$ 25,000/workshop)	25,000	1	25,000	1	25,000	1	25,000	1	25,000	1	25,000	2	50,000	3	75,000
	Sub-total			**44,000**		**44,000**		**48,000**		**44,000**		**48,000**		**94,000**		**125,000**
National, sectoral and enterprise level data collection	National experts undertaking national, sectoral and enterprise level consumption data (US$ 2,000/w.m.)	2,000	5	10,000	5	10,000	10	20,000	5	10,000	10	20,000	18	36,000	24	48,000
	Local travel	5,000	1	5,000	2	10,000	3	15,000	2	10,000	3	15,000	4	20,000	6	30,000
	International experts to analyze the data collected (US$ US$15,000/w.m.), incl. international travel	15,000	1	15,000	1.00	15,000	1	15,000	1.00	15,000	1	15,000	1	15,000	2	30,000
	Sub-total			**30,000**		**35,000**		**50,000**		**35,000**		**50,000**		**71,000**		**108,000**

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	Cost	#	Cost	#	cost	#	cost	#	cost	#	cost
Strategy Development	National expert (sectoral) to investigate the availability of alternatives and assist in the development of phase out scenarios (US$ 2,000/w.m.)	2,000	2	4,000	4	8,000	6	12,000	4	8,000	6	12,000	7	14,000	10	20,000
	International experts (sectoral) advise on the selection of alternatives and develop phase out scenarios (US$ US$15,000/w.m.), incl. international travel	15,000	1	15,000	1	15,000	1.00	15,000	1	15,000	2.00	30,000	2	30,000	3	45,000
	Stakeholder consultation workshops	25,000	1	25,000	1	25,000	1	25,000	1	25,000	1	25,000	2	50,000	3	75,000
	Sub-total			**44,000**		**48,000**		**52,000**		**48,000**		**67,000**		**94,000**		**140,000**

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	**Cost**	**#**	**Cost**	#	cost	#	cost	#	cost	#	cost
Investment and TAS project preparation	National expert to collect all enterprise level baseline data required for project preparation (US$ 2,000/w.m.)	2,000	2	4,000	4	8,000	6	12,000	6	12,000	8	16,000	11	22,000	14	28,000
	International expert to visit selected enterprises and prepare phase out projects (US$ US$15,000/w.m.), incl. international travel	15,000	**1**	15,000	2	30,000	3	45,000	2	30,000	3	45,000	3	45,000	6	90,000
	Sub-total			**19,000**		**38,000**		**57,000**		**42,000**		**61,000**		**67,000**		**118,000**
Sub-total for all components				**137,000**		**165,000**		**207,000**		**169,000**		**226,000**		**326,000**		**491,000**
Management, coordination and monitoring of the HPMP preparation	Project coordinator, database creation, telecommunication, office costs, incidentals	**20% of overall HPMP cost**		**27,400**		**33,000**		**41,400**		**33,800**		**45,200**		**65,200**		**98,200**
TOTAL Cost of HPMP preparation				**164,400**		**198,000**		**248,400**		**202,800**		**271,200**		**391,200**		**589,200**

Country	Consumption	Total Funding Request, US$	UNIDO funding request, US$	Agencies involved
Zero Consumption				
Albania	0	164,400	164,400	UNIDO single
Korea DPR	0	164,400	164,400	UNIDO single
Sudan	0	164,400	164,400	UNIDO single
	sub-total	493,200	**493,200**	
Servicing Consumption Only				
below 6				
Eritrea	1	198,000	198,000	UNIDO single
Macedonia	2.4	198,000	198,000	UNIDO single
Madagascar	2.6	198,000	70,000	UNEP lead
Nicaragua	3.4	198,000	198,000	UNIDO single
Niger	0.8	198,000	128,000	UNEP cooperating
sub-total		990,000	**792,000**	
6 to 100				
Servicing and Manufacturing				
Below 6				
Moldova	0.7	202,800	80,000	UNDP lead
Montenegro	1.3	202,800	202,800	UNIDO single
Turkmenistan	5.6	202,800	202,800	UNIDO single
	Sub-total	608,400	**485,600**	
6 to 100				
Algeria	6.6	271,200	271,200	UNIDO single
Bahrain	28.7	271,200	100,000	UNEP lead
Bosnia and Herzegovina	10	271,200	271,200	UNIDO single
Cameroon	10.2	271,200	271,200	UNIDO single
Croatia	10.4	271,200	271,200	UNIDO single
Honduras	12.2	271,200	148,000	UNEP cooperating
Jordan	55.7	271,200	271,200	UNIDO single
Kenya	42.5	271,200	100,000	UNEP lead
Libya	28.5	271,200	271,200	UNIDO single
Morocco	49.8	271,200	271,200	UNIDO single
Nigeria	35.8	271,200	100,000	UNDP lead
Oman	32.2	271,200	148,000	UNEP cooperating
Pakistan	65.5	271,200	100,000	WB lead
Qatar	15	271,200	148,000	UNEP cooperating
Senegal	9.6	271,200	271,200	UNIDO single
Serbia	9	271,200	271,200	UNIDO single
Syria	49	271,200	271,200	UNIDO single
Tunisia	31	271,200	271,200	UNIDO single
		4,881,600	**3,827,200**	
101 to 500				
Argentina	248	391,200	120,000	UNDP lead
Egypt	256	391,200	391,200	UNIDO single
Indonesia	299.9	391,200	80,000	UNEP lead, WB cooperating

Country	Consumption	Total Funding Request, US$	UNIDO funding request, US$	Agencies involved
Iran	166.5	391,200	80,000	UNDP lead, UNEP & GTZ cooperating
Kuwait	286.3	391,200	180,000	UNEP lead
Malaysia	383	391,200	120,000	UNDP lead
South Africa	222	391,200	391,200	UNIDO single
Venezuela	125	391,200	391,200	UNIDO single
Yemen	102.7	391,200	180,000	UNEP lead
		3,520,800	**1,933,600**	
501 to 1200				
India	592.5	589,200	100,000	UNDP lead, UNEP and GTZ cooperating
Mexico	1425	589,200	350,000	UNDP cooperating
Saudi Arabia	736	589,200	400,000	UNEP cooperating
Turkey	850	589,200	589,200	UNIDO single
		2,356,800	**1,439,200**	
TOTAL		12,850,800	**8,970,800**	
China			582,500	
GRAND TOTAL			**9,553,300**	

Description of the Role and Responsibility of a Lead Agency for the Preparation of an HPMP

Paragraphs 55 to 58 of document 54/53 containing the draft guidelines for the preparation of HCFC phase out management plans (HPMPs) outline the requirement for project coordination and management including monitoring and evaluation during the preparation of an HPMP. It requires Countries to

- Describe the management structure for the implementation of the HPMP
- Establish a project management unit.
- Assign the roles to be assumed by government bodies, industry bodies, academic institutions and consultants.
- Designate a government entity to which the management body would be held accountable

In defining the lead implementing agency's roles and responsibilities, UNIDO carefully considered the requirements stipulated in the guidelines for the preparation of the HPMPs and specifically those relating to the project coordination and management. Accordingly, these can be summarized below:

The Lead IA in close cooperation with the Government will be responsible for a range of activities as follows:

- Draw up the modality, organizational structure and time schedule of the preparation of HPMP.
- Prepare questionnaires for data survey.
- Assist the Country in developing a consistent long-term strategy that provides an overall direction and includes a list of critical actions and performance indicators to achieve the HCFC phase-out targets.
- Provide assistance in formulation of policy, capacity building and management issues governing HCFC consumption, import and production in the country. Assist the Country in preparing a strategy for the management of HCFC supply and demand including formulation and timely adoption of quota system for HCFCs and regulating import of HCFC containing goods.
- Support and advise the country in collection, compilation and analysis of data related to national level HCFC consumption;
- Assist the Country in elaborating a concrete prioritized approach to implement stage one of the HPMP describing specifically and comprehensively how the Country intends to meet the initial HCFC control measures in 2013 and 2015.
- Assist in formulation of strategic and policy level technical support activities related to screening of and establishing criteria for the selection of alternative substances, technologies and modalities of technology transfer as required.
- Implement all enterprise and sectoral level data collection, survey and program formulation activities as well as selection of alternative substances, technologies and formulation of investment projects in the sector(s) assigned to the Lead IA.
- Coordinate and facilitate the enterprise and sectoral level data collection, survey and program/project formulation work assigned to the cooperating agencies in the respective sectors in order to ensure the overall consistency of the HPMP
- Assist the country in designing a comprehensive monitoring system controlling the functioning of the licensing system.
- Organize stakeholder consultation meetings and ensure the participation of all stakeholders

- Prepare a fund mobilization strategy on a country-by-country basis taking into account the needs and the available sources of potential co-funding and financial incentives
- Carry out required supervision missions
- Based on the inputs from the cooperating agencies and the national stakeholders prepare and discuss and agree upon with the stakeholders on the draft and the final versions of the HPMP to be submitted to the Executive Committee
- Submit the HPMP to the ExCom, lead the discussions with the Secretariat and ExCom, provide clarification, undertake modifications etc.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

55th Executive Committee of the
Multilateral Fund for the Implementation
of the Montreal Protocol

UNIDO 2008 Work Programme Amendment

55th ExCom

Country	Type	Substance	Title of Project	Requested ammount USD	A.S.C USD	Total (incl ASC) USD	A. S. C. %	P. D.	Cooperation with IAs
Institutional Strengthening									
Montenegro	INS	CFC	Institutional Strengthening	60,000	4,500	64,500	7.5	24	Single Agency
			Institutional Strengthening Total	60,000	4,500	64,500			
MDI Project preparation									
Algeria	PRP	CFC	MDI Project preparation	30,000	2,250	32,250	7.5	12	Single Agency
Venezuela	PRP	CFC	MDI Project preparation	40,000	3,000	43,000	7.5	12	Single Agency
Syria	PRP	CFC	MDI Project preparation	40,000	3,000	43,000	7.5	12	Single Agency
			MDI Project preparation Total	110,000	8,250	118,250			
MDI Transitional Strategy									
Korea, DPR	TAS	CFC	MDI Transitional Strategy	30,000	2,700	32,700	9	12	Single Agency
Mongolia	TAS	CFC	MDI Transitional Strategy	30,000	2,700	32,700	9	12	Single Agency
			MDI Transitional Strategy Total	60,000	5,400	65,400			
Methyl Bromide Technical Assistance									
Colombia	TAS	MBR	Methyl Bromide Assistance	40,000	3,600	43,600	9	12	Single Agency
			Methyl Bromide Assistance Total	40,000	3,600	43,600			

Country	Type	Substance	Title of Project	Requested ammount USD	A.S.C USD	Total (incl ASC) USD	A.S.C. %	P.D.	Cooperation with IAs
Preparation HCFC Phase out Management Plan (HPMP)									
Albania	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Algeria	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Argentina	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating ($ 691,763)
Bahrain	PRP	HCFC22/141b	Phase out Management Plan	61,000	4,575	65,575	7.5	12	UNEP lead
Bosnia and Herzegovina	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Cameroon	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
China	PRP	HCFC22/141b	Phase out Management Plan	580,250	43,519	623,769	7.5	12	UNDP lead, WB/UNEP cooperating
Croatia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Egypt	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Eritrea	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Honduras	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP cooperating
India	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating
Indonesia	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating
Iran	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Iraq	PRP	HCFC22/141b	Phase out Management Plan	299,302	22,448	321,750	7.5	12	UNEP lead
Jordan	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Kenya	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Korea, DPR	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Kuwait	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Libya	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Macedonia, FYR	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Madagascar	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Malaysia	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Mexico	PRP	HCFC22/141b	Phase out Management Plan	321,750	24,131	345,882	7.5	12	UNDP cooperating
Moldova	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNDP lead
Montenegro	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Morocco	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Nicaragua	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Niger	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP cooperating
Nigeria	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Oman	PRP	HCFC22/141b	Phase out Management Plan	190,000	14,250	204,250	7.5	12	UNEP cooperating
Pakistan	PRP	HCFC22/141b	Phase out Management Plan	321,750	24,131	345,881	7.5	12	World Bank Lead
Qatar	PRP	HCFC22/141b	Phase out Management Plan	127,500	9,563	137,063	7.5	12	UNEP cooperating
Saudi Arabia	PRP	HCFC22/141b	Phase out Management Plan	547,000	41,025	588,025	7.5	12	UNEP cooperating
Senegal	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Serbia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
South Africa	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Sudan	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Syria	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Tunisia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Turkey	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Turkmenistan	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Venezuela	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Yemen	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
			Phase out Management Plan Total	12,225,764	916,932	13,142,696			
			Grand Total	12,495,764	938,682	13,434,446			

Algeria: Request for technical assistance to prepare CFC phase-out project in manufacture of Aerosol Metered Dose Inhalers (MDIs) and MDI transition strategy

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

Name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
Growth patterns of CFC-MDI production over the past five years;
Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
Each production facility's plan for phasing out CFC consumption; and
The number of non-CFC MDIs and DPIs sold or distributed within the Party, by active ingredient, brand/manufacturer, and source.

On behalf of the Government of Algeria, UNIDO is submitting a request for the preparation of an MDI conversion project as well for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI production and consumption sectors. Data gathered showed that Algeria does manufacture CFC MDIs and also imports them. It also showed that the trends of both CFC manufacture and non-CFC MDIs imports are increasing.

The objectives of the future project would be to phase-out the use of CFC-11 and CFC-12 in manufacture of Salbutamol, as Aerosol Metered Dose Inhalers (MDIs) at the Algerian Pharmaceutical Laboratory (LPA). The conversion of Algerian Pharmaceutical Laboratory (LPA) to the non-CFC based MDl product with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population in Algeria and thus facilitating access to vital medication for poor people in this country. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Algeria owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and environment.

The CFC National Phase-out Plan for Algeria was approved by 53rd ExCom meeting in November 2007 and resulted in the complete phase-out of CFCs between 2007 and 2010. The project addressed all the remaining consumption of CFCs, which was 302.6 ODP tonnes and marginal other ODS (Methyl Chloroform (TCA)), which was 96.5 ODP tonnes. The project included training, technical assistance and investment activities. The ODS consumption for the MDI sector (5.96 MT of CFCs in 2006) was not addressed in this project due to its small consumption quantity used in the production of only one MDI Salbutamol product. Another reason is that the CFC consumption, which is mostly in the refrigeration sector was controlled by the NOU of the Ministry for Environment and the CFC consumption in the pharmaceutical sector had to be controlled by the Ministry of Health. The NPP would allow Algeria to phase-out its CFCs consumption and ODS consumption listed under Annex B groups I & II by January 2010 and to phase out marginal Methyl Chloroform (TCA) consumptions by January 2015. The project budget is US$ 921,500.

2. Chronic respiratory diseases in Algeria

In middle-income countries, such as Algeria, COPD and asthma are emerging as public health problems. However, the prevalence of COPD is probably underestimated, since it is not usually diagnosed until it is clinically apparent and moderately advanced. COPD affects men more frequently than women, usually appears after 45 years of age, and increases in frequency with age. Tobacco smoking is the single most important factor in the genesis of COPD and is responsible for more than 75% of cases worldwide but other environmental risk factors are also known. In addition, COPD is associated with acute respiratory infections in children and low socioeconomic status. Substantial impairment of lung function is also often found in patients cured of tuberculosis, but with extensive residual fibrosis. The Asthma prevalence in Algeria is about 4.0 %.

3. Name of nationality owned CFC-MDI manufacturing facilities, the date when the CFC production lines were established and the production capacity of each production line.

The Algerian Pharmaceutical Laboratory LPA, the producer of MDIs in Algeria is 100% Algerian owned. It was founded in 1991.

The address of the company in Algeria:
LABORATOIRE PHARMACEUTIQUE ALGERIEN (LPA)
Z,I Boudouaou Est W.Boumerdes
35400 Algérie
Switchboard Phone Number: +213 24 84 32 20
Supply Direction Phone Number : +213 24 84 39 49
Fax Number : +213 24 84 24 92

The company produces only one type MDI, i.e. Salbutamol and consumed only 8.58 MT of CFCs in 2007.

SALBUTAMOL is being produced under the license from the laboratory CHIESI, Italy. LPA owns one line of aerosol production. It came into service in 2005. The production capacity of this line is 5 million units/year.

4. Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/year) and growth patterns of CFC-MDI production over the past five years

The Algerian Pharmaceutical Laboratory (LPA) consumes both CFC-11 and CFC-12 in the manufacture of aerosol MDIs. The CFC-11 is used for the preparation of an aerosol suspension of the active ingredient to facilitate filling the precise quantity into the open aerosol MDI container, after which the MDI aerosol container is closed with the aerosol metering valve, and the CFC-12 that acts as the aerosol "propellant" is injected into the aerosol container under pressure through the metering valve. This production process applies for all CFC aerosol products according to Algerian Health Ministry, specifications for the MDI product - Salbutamol.

Table 2. Manufactured CFC - MDI product

Active Ingredient	Description	Quantity	Presentation
Salbutamol	Aerosol suspension	Each inhalator contains Salbutamol 20mg or equivalent.	Inhalator flask with 200 doses of 100 mcg

4.1. Annual Consumption of CFC Propellants Used in Production

The CFC Consumption at LPA, and units produced by year is given in the table below for Year 2006 and 2007.

Table 3. Annual CFC consumption and MDI units produced in 2006 and 2007

Year	**2006**	**2007**
CFCs Consumption (Tons)		
CFC- 11	1, 650	2, 370
CFC -12	4, 310	6, 210
Total CFC annual consumption	5, 960	8, 580
Units manufactured		
Salbutamol (VENTMAX)	333 000	480 000

5. Existing equipment installed to manufacture CFC-MDI and alternatives contemplated

5.1. Existing workshop equipment for production of Ventmax

The initial installation of the line for MDI production was in 2005 and the first actual MDI production was launched in 2006.

The company is applying the established CFC-MDIs formulation and filling technology in the MDI production line. The production line was equipped from well known European suppliers:

Table 4. Process equipment

N° EQUIPMENT	EQUIPMENT	MAKE/MODEL	YEAR
01	FILLING MACHINE	COSTER 6AGV/M/PHARMA	2004
02	PREPARATION TANK 100L	PELLEGRINI	2004
03	PRODUCT RECIRCULATION PUMP	CSF	2004
04	TANK FOR EXCIPIENTS PRE-DISPERSION AND CONCENTRATE SUSPENSION PREPARATION WITH HOMOGENIZER SILVERSON	GRAMI	2004
05	INSTALLATION ON LOADING CELL	PELLEGRINI	2004
06	FILTER (PROTECTION OF THE PUMP)	/	2004
07	PUMP 25-PZG FOR F12	COSTER	2004
08	ACCUMULATOR WITH MEMBRANE	COSTER	2004
09	PUMP 25-PZG FOR F11	COSTER	2004
10	FREON 11 TANKS	/	2004
11	ACCUMULATEUR WITH MEMBRANE	COSTER	2004
12	FREON 12 TANKS	/	2004
13	PUMP FOR FREON 12 TRANSFER	COSTER	2004
14	HEAT EXCHANGERS FOR FREON 11 AND 12	/	2004
15	WORKING STATION WITH LAMINAIR AIR FLOW HOOD	STERIL	2005

Table 5. Packaging equipment

N° EQUIPMENT	EQUIPMENT	MAKE/MODEL	YEAR
16	CONVEYOR BELT	COSTER	2004
17	LOADING TABLE N°1	COSTER	2004
18	CHECKWEITHER NR1 AS	RAMSEY	2004
19	LABELING MACHINE	ETIPACK	2004
20	TRAY LOADING	COSTER	2004
21	LOADING TABLE N°2	COSTER	2004
22	CHECKWEITHER NR2 AS	RAMSEY	2004
23	CHEKED CAN IN CARTON BOX	COSTER	2004
24	WORKING TABLE FOR MANUEL SPRAY TEST OF VALVES	MERCURY	2005
25	CARTONING MACHINE AV	CAM	2004
26	LABELING MACHINE N°2	ETIPACK	2004

6. Plan for phasing out CFC consumption in the production facility

6.1. Replacement technology and equipment

The most acceptable replacement technology is the use of HFA instead of CFC as a propellant in the MDI production. This technology is now widely used in most pharmaceutical companies worldwide and all new drugs formulations are based on this propellant.

Therefore, LPA will need the HFA technology with regard to MDI formulation and new filling machines to be installed at its premises. A corresponding training the working staff on the new machinery is also needed. The existing machinery cannot be retrofit to manufacture HFC MDIs, but still there are some components of the line could be used.

6.2. Equipment required for the HFA MDI production

A whole production line will include:
1 - HFA circulating pump
2 - HFA pump
3 - Single aerosol assisted manual filling installation

6.3. Equipment in place and not needed to be replaced

1 - Labelling machine
2 - Checkweigher

6.4. Plan for phasing out CFC consumption in the production facility

New productions techniques and processes for the conversion of most of LPA CFC MDIs into HFC MDIs LPA will need completely different production equipment.

The HFC 134a will replace both CFC-11 and CFC-12 in the CFC MDI formulation.
Due to the gas nature of the HFC-134a at the normal atmospheric pressure the suspension (HFC-134a /active ingredients) preparation would have to be made in a pressurized preparation mixer, then the prepared slurry suspension would be dosed through the filling machine into the aerosol can.

The key transition program steps for technology transfer for LPA are:

• Agree specifications for an assisted manually operated pressure filling line, which has a capacity: with dosing valve 5 -10 cans/minute (depending as on the volume and valve to be filled).

• Procure, install commission and validate the production line.
• Agree performance based product specifications for the developed product. The objective is to replace the current CFC Salbutamol marketed product with an HFA equivalent product that will meet the current regulatory requirements of the Algerian Health Authority.
• Selection of all materials and primary packaging components (valve, canister and actuator), not the secondary packaging components (carton, package insert etc.). The selection process and evaluation must take in to consideration local and/ or current suppliers that may offer a more cost competitive product.
• Package and formulation development supported by short term, performance data. Data package to be reviewed with client for acceptability prior to undertaking stability phase.
• Subject to agreement generation of a minimum of 6 months 40C 75RH unprotected stability/performance data on the selected package/ formulation. The full stability test data package to be reviewed with LPA for acceptability.
• Generation of all required documentation and reports, technology transfer of all analytical and manufacturing methods.
• Verification of successful technology transfer of each product to LPA manufacturing facility. Including verification of analytical method transfer, assistance and training on-site of analytical and manufacturing personnel.
• Manufacture of Registration/ Stability batches of the product(s).
• Supply data suitable for submission to Algerian Health Authorities for marketing approval.
• De-commissioning of all CFC dedicated manufacturing equipment and exhaustion of residual CFC stocks.

7. Number of non-CFC and CFC-free MDIs and DPI sold or distributed by active ingredient, brand/manufacturer, and source

The table below presents the quantities of various types of CFC MDIs, HFA MDIs and DPIs imported into the country in 2004 - 2007.

The total amount of all imported inhalators in Algeria in 2007 was about 3.8 million units including CFC and HFA MDIs and DPIs, although the quantities of CFC-free MDIs exceeded the quantities of CFC MDIs. This tendency was conditioned by the implementation of the Montreal Protocol Agreement. At the time of the project formulation UNIDO would approach the Drug Administration for detailed discussions on the Transitional Strategy formulation and implementation and precise analyses of the MDI quantities imported into the country in the past years. The Ministry confirmed that the two types of MDIs, i.e. CFC and CFC-free MDIs are available on the local market. Small quantities of DPIs are also available on the market, although too expensive for the majority of Algerian population.

The LPA des not export MDIs to other countries in the region.

Table 7. Imports of MDIs/DPIs into Algeria in 2004-2007

7.1. Imports of MDIs/DPIs into Algeria in 2004

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	209,704	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	28,000	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/BOUFF	FL/80DOSES	8,852	UK
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	99,249	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	19,500	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	100,000	ITALY
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	4,000	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	1,000	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	UK
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	5,000	FRANCE
IPRATROPIUM BROMURE	Propellant: monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	9,000	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	20,000	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	139,832	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,410,958	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	816,499	UK
SALBUTAMOL	HFA 1341a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,651	Italy
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	242,107	UK

SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	300,000	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,200	Italy
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,500	FRANCE
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	14,499	UK
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	250/50µG	FL/60DOSES	59,991	UK
SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	20,000	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	UK
BUDESONIDE	HFA 134a	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	34,880	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	30,641	FRANCE
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	149,993	FRANCE

7.2. Imports of MDIs/DPIs into Algeria in 2005

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Producer	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF.	FL/200DOSES	324,560	GSK	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	41,000	CIPLA	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	7,500	GSK	UK
BECLOMETHASONE	Norflurane (HFA)	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	220,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	18,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	1,000	CHIESI	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	GSK	UK
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	5,500	GSK	FRANCE
IPRATROPIUM BROMIDE	Propellant : monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	12,000	BOEHRINGER	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	22,340	CIPLA	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,100	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,600,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	28,000	CHIESI	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	250,000	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	220,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,600	CHIESI	FRANCE
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,300	GSK	FRANCE

SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	16,546	GSK	UK
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	250/50µG	FL/60DOSES	59,991	GSK	UK
SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	22,000	GSK	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	GSK	UK
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	36,000	CIPLA	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	34,000	ASTRA ZENECA	FRANCE
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	160,000	SERVIER	FRANCE

7.3. Imports of MDIs/DPIs into Algeria in 2006

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Producer	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF.	FL/200DOSES	246,000	GSK	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	34,0000	CIPLA	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	8,852	GSK	UK
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	30,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	2,500	CHIESI	FRANCE

BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	12,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	124,000	CHIESI	ITALY
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	10,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	2,100	CHIESI	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	GSK	UK
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	15,100	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	10,500	GSK	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	76,432	CHIESI	FRANCE
IPRATROPIUM BROMURE	Propellant : monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	10,000	BOEHRINGER	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	234,657	CIPLA	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	2,650,00	GSK	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	589,000	GSK	UK
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	25,000	CHIESI	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	244,453	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	180,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,200	CHIESI	FRANCE
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,500	GSK	FRANCE
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	87,567	GSK	UK

SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	23,000	GSK	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	GSK	UK
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	20,000	CIPLA	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	28,000	ASTRA ZENECA	FRANCE
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	16,000	CIPLA	INDIA
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	78,657	SERVIER	FRANCE

7.4. Imports of MDIs/DPIs into Algeria in 2007

Producer	Country	Brand name	Generic name	Type	Quantity 2007	Dosage	Strength	CFC/HFA MDIs and DPIs
CHEISI S.A.	ITALY	CLENIL 250	BECLOMETHASONE	Aerosol	239.045	250µG/puff	FL/200 doses	Norflurane
ASTRA	FRANCE	BRICANYL	Terbutaline	Aerosol	21.678	250 µG /puff	FL/200 doses	(Freon 11), cryoflurane (Freon 114), (Fréon 12)
ASTRA	FRANCE	PULMICORT	BECLOMETHASONE	Aerosol	40.931	200µG/puff	FL/200 doses	(CFC 11), (cryofluorane or CFC 114), (CFC 12)
GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	50µG /dose	FL/120 doses	Norflurane (tetrafluoroethane or HFA-134a).

GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	125µG /dose	FL/120 doses	Norflurane (tetrafluoroethane or HFA-134a).
GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	250µG /dose	FL/60 doses	Norflurane (tetrafluoroethane or HFA-134a).
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)Fluticasone (propionate)	Inhaler Powder	91.474	500 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)/Fluticasone (propionate)	Inhaler Powder	219.963	250 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)/Fluticasone (propionate)	Inhaler Powder	38.681	100 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
BOEHRINGER INGELHEIM	GERMANY	ATROVENT	IPRATROPIUM BROMURE	Pressurised Flask Inhaler Suspension	94.764	20µG Dose	FL/200 doses	Propellant : monofluorotrichloromethane
NOVARTIS PHARAM S.A.	FRANCE	FORADIL	Formotérol	Powder for Inhaler	162.3	12 micro G	B/30 ET B/60	Powder for inhalation in capsules
CHEISI S.A.	ITALY	BECLOJET	BECLOMETASONE	Oral Inhaler Suspension	22.499	250 µG / Breath	FL/200 doses+ Integrated inhalation chamber	Norflurane (HFA)
PFIZER	FRANCE	COLLU-HEXTRIL	HEXETIDINE	Oral Medication	587.646	0.20%	FL/40ML	Nitrogen
BOUCHARA-RECORDATI	FRANCE	HEXASPRAY	Biclotymol	Oral Medication	166.276	0,75MG / 30G	Pressurised Flask/30G	Nitrogen

FUMOUZE	FRANCE	STERIMAR	Microdiffusion physiologique d'eau de mer	Oral Medication	-	Sea water: 31,82ml, Purified water qsp 100ml,	F/100 ml	Nitrogen
Laboratoires GILBERT	FRANCE	MARIMER	Eau de mer isotonique microdiffusée	Sterilized Sea Water physiologic al Solution	-	Sea water: 31,82mlPurifi ed water qsp 100ml,	Pulverising Flask of 100 ml	Nitrogen
Laboratoires PIERRE FABRE MÉDICAMENT Laboratoire Pierre Fabre Oral Care	FRANCE	ELUDRIL	Chlorhexidine, Tétracaïne	Oral Medication	-	50 mg/15 mg/100ml	FL/55ml	Nitrogen

8. The Transition Strategy for the elimination MDIs with CFCs and the introduction of the replacement CFC MDIs in Algeria

The national transition strategy (to be prepaed under the NPP) as a part of the MDI conversion project will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of the Ministry of Health, physicians, health professionals, pharmaceutical companies/association and the community.

The education and sensitising campaign for the introduction of new products (HFA MDIs) will therefore be both necessary and challenging in this situation. Considering the above-mentioned elements the implementation of an education programme involving health professionals, patients, their families and the community from the very beginning becomes a priority, led by the Ministry of Health and Medical Education.

9. Project duration period

Until the new production line is installed and is ready for production of HFA MDIs on the commercial basis, LPA would continue the production of CFC MDIs. The first step would be to start with the conversion of one product, which would likely be " VENTMAX " Salbutamol. The conversion period would take about two years until LPA finishes all the tests and obtaining a license and marketing authorization from the Ministry of Health of Algeria provided that a technology provider selected by UNIDO would complete the task of new products formulation and 6 months testing at its premises.

10. Urgent conversion to HFA production is needed

For Algeria and particularly for the health sector and environment the project is of a very high importance, because the Government of Algeria need to urgently convert this company to non-CFC MDI production in order to provide locally produced cheaper MDIs for thousands of asthma and COPD patients in Algeria, specially those that have low income.

Another urgency to have HFA MDIs available in the country is the absence of imported inhalers in Algeria and if they could be even available in the black market they are not affordable for most of Algerian population due to their higher price in comparison with those produced by the LPA. The low income of the majority of the people in Algeria and the absence of good health insurance programs in most of the countries of the region characterize the pricing policy of the LPA with regard to the MDIs.

Revised
PTC/MEA/VS
UNIDO
June 2008

DPR Korea: Technical assistance to prepare MDI transition strategy (US $30,000)

1. Background

DPR Korea has a planned economy, supervised by the National Planning Commission.

The Ministry of Public Health is responsible for the supervision of the State health services. There is no private sector.

The number of asthma patients in DPRK is stable. Around 4 % of the population suffer from Asthma and COPD, i.e. 900,000 people out of about 23,000,000 total population.

In order to be prepared for any problems associated with the replacement of CFC MDIs with alternatives such as HFA MDIs and powder inhalers, the Ministry of Public Health expressed their interest in having a transition strategy formulated by UNIDO.

2. Project description

The Government of DPR Korea has requested UNIDO to formulate the Transitional Strategy for the MDI Sector. The Government confirmed their interest in having such a strategy formulated by UNIDO and also provided data on the MDI imports in DPRK for the past three years.

On behalf of the Government of DPR Korea, UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector.

Data gathered by UNIDO show that DPR Korea does not manufacture CFC MDIs. The available data indicates that 2,311,600 units were imported in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007. These imports are from Altayvitamin Company in the Russian Federation. The generic names are Salbutamol and Beclamethasone.

The incidences of chronic destructive pulmonary disease (COPD) and asthma in DPR Korea are stable. A steady supply of MDIs is needed to meet patients' needs.

3. National MDI Strategy

The national strategy on replacement of CFC-based MDIs with alternatives is envisaged as follows:

- Continued analysis of MDI market consumption, sources of supply and estimates of future trends.
- Evaluation of alternative products and their economic impact on the State health services.
- Supervise the transition to alternatives.
- Regulations will be introduced to support the phase-out of CFC-based MDIs and to ensure the monitoring of imports of MDIs, conforming to the provisions of the Montreal Protocol and its amendments..
- A programme to raise physician awareness and patient acceptance of alternatives to CFC-MDIs.
- The requested funding of US$ 30,000 for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs.

4. Funding

The requested funding of US$ 30,000 for the development of an MDI transition strategy will allow the establishment of a clear schedule for import of alternatives to CFC-MDIs.

5. Survey of MDIs in DPR Korea

In support of their submission and based on decision 51/34, UNIDO has worked together with the Ministry of Public Health to survey the situation with regards to the supply of MDIs and their non-CFC equivalents in DPR Korea. The situation is reflected in Exhibit 1 attached on page 3 and is as follows:

- CFC MDIs are available but there are no non-CFC equivalents, neither HCFC products nor powder inhalers.
- Imports of CFC MDIs decreased slightly from 2005-2007. 2,311,600 units were imported in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007.
- Prices for the last three years have remained stable.

A comprehensive table listing CFC MDIs imported, sold or distributed within the country, identified by active ingredient, manufacturer and source, is summarised in Exhibit 1 below:

6. Summary

DPR Korea does not manufacture CFC MDIs.

Imports of CFC MDIs were 2,311,600 units in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007. The source was Russia and the price was a uniform US$ 2 per unit. Generic names are Salbutamol and Beclamethasone.

The number of asthma patients in DPRK is stable. Around 4 % of the population suffer from Asthma and COPD, i.e. 900,000 people.

The project preparation request for US$ 30,000 is being submitted to enable the smooth transition to non-CFC MDIs in DPR Korea, therefore phasing out CFC consumption in the MDI sector.

PTC/MBR/VS
UNIDO
May 2008

Exhibit 1: Market share of MDIs

MDI brand name	Active ingredient	Manufacturer	Importer	Cost of one MDI, US$	Propellant	MDI units imported/year		
						2005	2006	2007
Ventalex	Salbutamol	Altaivitaminy, Russia	Mannyon Public Health Company	2	CFC	2,126,000	2,013,400	1,867,400
Beclex	Beclamethasone	Altaivitaminy, Russia	Mannyon Public Health Company	2	CFC	185,600	200,040	196,650
MDI brand name	**Date approved by local drug administration**	**Date authorised for marketing**		**Date launched on the territory of the country**				
Ventalex	Department of Drug Affairs, Ministry of Public Health	November 2004, 2005, 2006		February 2005, 2006, 2007				
Beclex	Department of Drug Affairs, Ministry of Public Health	November 2004, 2005, 2006		February 2005, 2006, 2007				

Source: Ministry of Public Health of DPRK

Project Concept

Country:	Mongolia
Title:	Technical Assistance to Prepare an MDI Transitional Strategy
Background:	UNIDO received an official Government request to prepare an MDI transitional Strategy in Mongolia
Project Duration:	12 months
Project Budget:	32,700 (including 7.5% Agency Support Costs)
Implementing Agency:	UNIDO
Coordinating Agency:	Ministry of Environment

Project Summary

1. Background

Mongolia is a country in transition from a planned economy to being market oriented.

The health services fall under the Ministry of Health.

The Government of Mongolia has requested UNIDO to formulate the Transitional Strategy for the MDI Sector. The Government confirmed their interest in having such a strategy formulated by UNIDO and also provided data on the MDI imports in Mongolia for the three years 2003-2005.

Mongolia imports MDIs from the Russian Federation. The generic name is Salbutamol.

The number of asthma patients in Mongolia is stable. Around 1.2 % of the population of 2,500,000 is reported to suffer from Asthma and COPD, i.e. about 30,000 people. This unusually low incidence in global terms may result from under-reporting and reluctance by the rural population to seek medical treatment from non-traditional sources.

In order to be prepared for any problems associated with the replacement of CFC MDIs with HFA MDIs, the Ministry of Health expressed their interest in having a transition strategy to be

formulated by UNIDO.

2. Project description

On behalf of the Government of Mongolia, UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector.

Data gathered by UNIDO show that Mongolia does not manufacture CFC MDIs.

There is an overall concern on the part of the Government of Mongolia and its health authorities about the MDI sub-sector. The incidences of chronic destructive pulmonary disease (COPD) and asthma are stable and there is a need to ensure a steady supply of MDIs to meet these patients' needs.

3. National Strategy

The national strategy on replacement of CFC-based MDIs with alternatives is envisaged as follows:

(a) Better study and analysis of current MDI market consumption, supply sources and future trends.

(b) Analysis of alternative products and their effects and health benefits.

(c) Co-operation with the main importers and the public health authorities to define affordable alternative medications.

(d) Development of multi-year national planning on imports to ensure a smooth transition to alternatives.

(e) Regulations will be put in place to support the phase-out of these ozone depleting products and to ensure the monitoring of imports of MDIs conforming to the provisions of the Montreal Protocol and its amendments.

(f) A programme to raise physician awareness and patient acceptance of alternatives to CFC-MDIs. This will involve training and targeted awareness activities, to increase confidence and ensure acceptance of the alternative products by both patients and doctors.

Health authorities are in general not aware of the requirements of the Montreal Protocol to phase out CFCs in MDIs.

4. Funding

The requested funding of US$ 30,000 for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs.

5. Survey of MDIs in Mongolia

In support of their submission and based on decision 51/34, UNIDO has worked together with the Regulatory Agency of the Government, State Specialized Inspection Agency, Health Monitoring Bureau. The situation has been surveyed with regards to the supply of MDIs and their non-CFC equivalents in Mongolia and can be briefly described as follows:

(a) There is no manufacture of CFC or HCFC MDIs in Mongolia.

(b) Only imported CFC MDIs are available. There are no HCFC products and no powder inhalers.

(b) Imports of CFC MDIs were 10,000 units in 2003, 8,538 in 2004 and 6,480 units in 2005. The source was Russia and the price was US$ 2 per unit.

The country has a stable pricing for unit costs, as prices for the last three years for specific products have remained the same although the supplier has changed.

The reason for the sharp decline from 2003 to 2004 and then to 2005 is believed to have been over-stocking in 2003.

A comprehensive table listing CFC MDIs imported, sold or distributed within the country, identified by active ingredient, manufacturer and source, is summarised in Exhibit 1 below:

Exhibit 1 **MDIs in Mongolia**

Active ingredient	**Manufacturer**	**Propellant**	**MDI units imported/year**		
			2003	**2004**	**2005**
Salbutamol, aerosal-12ml	Moschimfarm, Russia	CFC		8,538	6,480
Salbutamol, aerosal-12ml	Altaivitamin, Russia	CFC	10,000		

Source - Regulatory Agency of the Government, State Specialized Inspection Agency, Health Monitoring Bureau

6. Summary

The project preparation request for US$ 30,000 is being submitted to enable the smooth transition to non-CFC MDIs in Mongolia, therefore phasing out CFC consumption in the MDI sector.

Imports of CFC MDIs were 10,000 units in 2003, 8,538 in 2004 and 6,480 units in 2005. The source was Russia and the price was US$ 2 per unit. Generic name is Salbutamol. Product had been over-stocked in 2003.

The number of asthma patients in Mongolia is stable. Around 1.2 % of the population of 2,500,000 is reported to suffer from Asthma and COPD, i.e. about 30,000 people. This unusually low incidence in global terms may result from under-reporting and reluctance by the rural population to seek medical treatment from non-traditional sources.

Project Concept

Country:	Syria
Title:	Preparation of MDI Project
Background:	UNIDO received an official Government request for the preparation of MDI project in Syria
Objectives:	To prepare a project to phase out CFC use in the production of MDIs in Syria.
Project Duration:	12 months
Project Budget:	43,000 (including 7.5% Agency Support Costs)
Implementing Agency:	UNIDO
Coordinating Agency:	Ministry of Environment

Project Summary

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

- Name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
- Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
- Growth patterns of CFC-MDI production over the past five years;
- Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
- Each production facility’s plan for phasing out CFC consumption; and

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

On behalf of the Government of Syria, UNIDO is submitting a request for the preparation of an MDI conversion project as well for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI production and consumption sectors. Data gathered showed that Syria does manufacture CFC MDIs and also imports DPIs. It also showed that the trends of both CFC manufacture and DPIs imports are increasing.

The objectives of the investment project would be to phase-out the use of CFC-11 and CFC-12 in manufacture of Salbutamol, Beclomethasone Dipropionate, Beclomethasone Dipropionate plus Salbutamol, Fluticasone Propionate, Salmeterol and Salmeterol plus Fluticasone Propionate as Aerosol Metered Dose Inhalers (MDIs) at Kaspar-Chabani Pharma, which represent almost 100% of the consumption in the social security in Syria.

The conversion of Kaspar-Chabani Pharma to non-CFC based MDl products with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population and thus facilitating access to vital medication for millions of people. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Syria owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and environment.
Syria has no CFC production. All CFCs consumed for manufacturing and servicing purposes are imported mainly from developed countries and supplied through distributors, indenting agents and systems houses. The CFC National Phase-out Plan for Syria was approved by 49th ExCom meeting in 2006 and resulted in the complete phase-out of CFCs between 2006 and 2010. The cost of the project as approved was US$ 946,000 and it addressed all the remaining consumption of CFCs, which was 898.56 ODP tones (as of 2005). The project included training, technical assistance and investment activities. The ODS consumption in the MDI sector (25.71 MT of CFCs in 2005) was not addressed in this project. The NOU was not informed about the CFC consumption in the MDI production at K.C. Pharma, which is under control of the Ministry of Health. It is also believed that the major CFC consumption was in the refrigerator sector. Moreover, the CFC consumption in the aerosol and foam sectors was phased out in 2005. Acording to the NPP document the CFC consumption in the country was mainly in refrigeration manufacturing sector, though the consumption was reduced through implementation of the previously approved refrigeration management plan. With a series of activities proposed in the NPP, the service usage of CFCs will be

gradually reduced. With this arrangement, Syria achieved the 85% reduction target in 2007 and would achieve zero consumption by 2009 in terms of the CFC consumption. The total phase of CFCs in the MDI sector would take place in 2010.

KC Pharma’s CFC imports in 2007 were around 52 MT from a French company to cover the expected increase in demand in 2007-2008, and new orders have also been made. All of KC Pharma's CFC import requests were forwarded to the Ministry of Health in Syria due to the CFC specific role in inhalers production and in order to make customs clearance easer, since a pharmaceutical ingredient was considered by the Ministry of Health but not by the Ministry of Environment. Therefore, the NOU was not aware of the CFC consumption in the MDI sector.

2. Asthma and COPD in Syria

2.1. Population and economy

Population (2005): 18.6 million
Growth rate (2005): 2.45%
Literacy-92.5% - 87.9% - male and 73.9% - female
Health (2004): Infant mortality rate-17.1/1,000
Life expectancy- 68.47 years – male and 71.02 years - female
Workforce (6.1 million, 2004 est.): involved in providing services (including the government), in agriculture and industry and commerce.
GDP (2005nominal): $27.3 billion.
Real growth rate: 2.9%.
Per capita GDP: US$ 1,464.
Natural resources: Crude oil and natural gas, phosphates, asphalt, rock salt, marble, gypsum, iron ore, chrome, and manganese ores.
Agriculture: Products; cotton, wheat, barley, sugar beets, fruits and vegetables. **Industry:** Types-mining, manufacturing (textiles, food processing), construction, petroleum.
Trade:
Exports-US$10.2 billion: petroleum, textiles, phosphates, antiquities, fruits and vegetables, cotton. Major markets: EU, Arab countries, United States, Eastern and Central Europe.
Imports: US$10.8 billion: foodstuffs, metal and metal products, machinery, textiles, petroleum. Major suppliers-Russia, Turkey, Ukraine, China, U.S. and Japan.

2.2. Respiratory diseases in Syria

The main cause of COPD in Syria is smoking. But exposure to dusts in the workplace can also cause COPD, even if people don't smoke. SCTS’s (the Syrian Center for Tobacco Studies) population-based assessment of tobacco use in Syria showed that daily cigarette

smoking is the predominant form of smoking, affecting 51.4% of men and 11.5% of women, and that waterpipe smoking is gaining ground, affecting 20.2% of men and 4.8% of women. Waterpipe smoking is characterized by intermittent use and predominance among the young and affluent. A meeting with the Central Bureau for Statistics to check the percentage of the population using MDI products.

The prevalence of asthma in Syria is around 5-8% of the population and it is increasing at an average rate of around 5% per year. The respiratory disease child death rate in Syria is 42.55/100,000 inhabitants.

According to the Central Bureau for Statistics the 2005 statistics showed that 5.4% of Syrian population was using MDIs for asthma treatment or prevention, and the Bureau assumed that this percentage would be presently about 6%.

3. Name of nationality owned CFC-MDI manufacturing facilities, the date when the CFC production lines were established and the production capacity of each production line

Kaspar-Chabani Pharma also known as (K.C. Pharma) was first established in 1988 as a 100% Syrian owned company.

The plants and main offices of the company are located in Aleppo, which is 360 km north off Damascus, the capital of Syria.

The main production lines in the company are for products like: Syrups, Suspensions, Ear drops, Capsules, Tablets, Film Coated Tablets, Ovules, suppositories and CFC-MDIs.

The company is the sole producer of MDIs in Syria.
Currently the company occupies a land area of 13,000 square meters, with one factory
building area of 4000 square meters.

Company address

The company name is Kaspar and Chabani Pharma (K.C.Pharma).
Address: Haian Industry Zone , Aleppo – Syria.
Telephone Number: +963 21 2656062.
Fax Number: +963 21 2656562.
E-Mail Address: info@kc-pharma.com
Website: www.kc-pharma.com
Scientific Office: Aleppo – Syria.
Tel: +963 21 4444060 - +963 21 4444068.
Mailing Address: Kaspar-Chabani Pharma
P.O.Box: 3980, Aleppo - Syria
Telephone and fax number of contact person:

The general manager Mr. Joseph Kaspar
Tel: +963 21 2656062, +963 21 4444060, +963 21 4444068.
Fax: +963 21 2656562.

3.1. MDI production facilities

The initial installation of the line for MDI production was in 1998 and the first actual MDI production was launched in 1999. The company was using the established CFC-MDIs formulation and filling techniques. The production line was equipped from well known European suppliers, i.e.:

- Suspension preparation vessel 150 littres: Pietro Pelligrini (Italy)
- Filling Machine + CFC-11 pump + recirculating system + CFC-12 pump: Coster (Italy)
- Checkweigher : Thermo Ramsey Tecnoeuropa (Italy)
- Labeling machine: Neri (Italy)

3.2. MDI line production capacity and MDI products

The current CFC-MDI production equipment capacity is 3600 cans/hour, and about 8.5 million cans/year on a single production line, single shift per day. However, the actual MDI demand met by KC Pharma in Syria in 2007 was around 2.0 million MDIs per year.

Dates of approval and production of each product

Active ingredient	Date of establishment
Salbutamol	1999
Beclomethasone Dipropionate	1999
Beclomethasone Dipropionate + Salbutamol	1999
Fluticasone Propionate	2002
Salmeterol	2003
Salmeterol + Fluticasone Propionate	2004

4. Type of CFC MDI products manufactured, active ingredients used, annual production output (units/year) and growth patterns of CFC-MDI production over the past eight years

4.1. CFC-based MDI manufacturing process at KC Pharma

KC Pharma use both CFC-11 and CFC-12 in the production of aerosol MDIs.
CFC-11 is used for the preparation of suspension with active ingredients to smooth the progress of filling the exact amount of suspension into the open aerosol MDI container, and then the metering valve is placed onto the open container and crimped with the aerosol container. CFC-12, which is a propellant is injected into the container under pressure through the metering valve.

KC Pharma products specifications

Product Name	Composition	Presentation
Butovent Spray	Salbutamol BP 100 mcg/puff	200 doses
Clenil Forte Spray	Beclomethasone Dipropionate 250 mcg/puff	200 doses
Clenil Spray	Beclomethasone Dipropionate 50 mcg/puff	200 doses
Clenil Forte jet	Beclomethasone Dipropionate 250 mcg/puff	200 doses
Clenil Compositum Spray	Beclomethasone Dipropionate 50 mcg/puff Salbutamol BP 100 mcg/puff	200 doses
Asthmatide 50	Salmeterol 25 mcg/puff Fluticasone Propionate 50 mcg/puff	120 doses
Asthmatide 125	Salmeterol 25 mcg/puff Fluticasone Propionate 125 mcg/puff	120 doses
Asthmatide 250	Salmeterol 25 mcg/puff Fluticasone Propionate 250 mcg/puff	120 doses
Flusone 44	Fluticasone Propionate 50 mcg/puff	120 doses
Flusone 110	Fluticasone Propionate 125 mcg/puff	120 doses
Flusone 220	Fluticasone Propionate 250 mcg/puff	120 doses
Asthmerol	Salmeterol 25 mcg/puff	120 doses

As mentioned in paragraph 2.1 the initial installation of the aerosol MDI line was in 1998, but its first output was in 1999.

At the very beginning the growth was between 5-10% because the MDI products were new ones in the market but in years 2002-2004 the growth became around 10-15 % and it increased up to 15-20% in 2005-2006. The figures of 2007 show an unprecedented growth of 40

% due to many reasons; amongst them was the growing number of population and increasing numbers of the Iraqi refugees and the expansion of markets abroad.

Annual production figures 1999-2002 (in number of units) at K.C. Pharma

MDI products	**1999**	**2000**	**2001**	**2002**
Butovent Spray	487900	513000	543000	582000
Clenil Forte Spray	46900	49000	52200	55850
Clenil Spray	63700	66900	71000	75800
Clenil Forte jet	2900	3000	3200	3400
Clenil Compositum Spray	45500	47800	51000	54200
Total	646900	679700	720400	771250

Annual CFC consumption (1999-2002)

Year	1999	2000	2001	2002	2003
	Annual consumption by (MT)				
CFC-11	4.36	4.58	4.86	5.20	5.89
CFC-12	10.18	10.70	11.34	12.14	13.76
Total	14.55	15.29	16.20	17.35	19.66

Annual production figures 2003-2007

Product	2003	2004	2005	2006	2007
Butovent Spray	634000	697000	780400	874000	1235000
Clenil Forte Spray	61000	67000	75000	84000	99300
Clenil Spray	83000	90900	101800	114000	141000
Clenil Forte jet	3700	4100	4600	5100	-
Clenil Compositum Spray	59050	65000	72800	81500	104700
Asthmatide 50		4100	8200	6400	12400
Asthmatide 125		11600	25400	32600	49900
Asthmatide 250		7400	16900	23800	36200
Flusone 44	6100	4700	5500	7100	9500
Flusone 110	7500	11700	7600	14200	16800
Flusone 220	4900	7500	6800	10800	12700
Asthmerol	14600	32500	37800	39100	46200
Total	873850	1003500	1142800	1292600	1763700

Annual CFC consumption (1999-2007)

Year	2004	2005	2006	2007
	Annual consumption by (MT)			
CFC -11	6.77	7.71	8.72	11.90
CFC-12	15.79	17.99	20.35	27.76
Total	22.57	25.71	29.08	39.68

4.2. Existing equipment installed at KC Pharma to manufacture CFC-MDI

The list of existing line machinery and equipment for production of CFC products:

- Suspension preparation vessel (150 littres) is from Pietro Pelligrini (Italy)
- Filling Machine + CFC-11 pump + recirculating system + CFC-12 pump are from Coster (Italy)
- Checkweigher is from Thermo Ramsey Tecnoeuropa (Italy)
- Labeling machine is from Neri (Italy)

All these machines were purchased in 1998 when the company decided to start manufacturing CFC MDIs in Syria. It should be noted that the filling machine cannot be retrofitted to be compatible with a HFA MDI line.

4.3. Required HFA machines for the conversion plan

4.3.1. Replacement technology and equipment

The most acceptable replacement technology is the use of HFA instead of CFC as a propellant in the MDI production. This technology is now widely used in most pharmaceutical companies worldwide and all new drugs formulations are based on this propellant.

Therefore, KC Pharma will need the HFA technology with regard to MDI formulation and new filling machines to be installed at its premises. A corresponding training the working staff on the new machinery is also needed. The existing machinery cannot be retrofit to manufacture HFC MDIs, but still there are some components of the line could be used.

4.3.2. Equipment required for the HFA-based MDI production

A whole production line will include:
1 - Mixing Vacuum preparation vessel 150l for single-stage filling production
2 - HFA circulating pump
3 - HFA pump
4 - Aerosol filling machine Macromat P 2045

4.3.3. Equipment in place and not needed to be replaced

1-labelling machine
2-checkweigher

4.4. Plan for phasing out CFC consumption in the production facility

New productions techniques and processes for the conversion of most of KC Pharma CFC MDIs into HFC MDIs KC Pharma will need completely different production equipment.

The HFC-134a will replace both CFC-11 and CFC-12 in the CFC MDI formulation.
Due to the gas nature of the HFC-134a at the normal atmospheric pressure the suspension (HFC-134a /active ingredients) preparation would have to be made in a pressurized preparation mixer, then the prepared slurry suspension would be dosed through the filling machine into the aerosol can.

5. Project duration period

Until the new production line is installed and is ready for production of HFA MDIs on the commercial basis, KC Pharma would continue the production of CFC MDIs.
The first step would be to start with the conversion of one product, which would likely be "BUTOVENT" Salbutamol BP. The conversion period would take about one year until KC Pharma finishes all the tests with technical assistance from UNIDO and equipment installation, staff training and obtaining a license and marketing authorization from the Ministry of Health of Syria.

In parallel the conversion of other products could start, therefore the whole period of conversion would take about 2 years provided that a technology provider selected by UNIDO would complete the task of new products formulation and 6 months testing at its premises. Therefore, one additional year needs to be taken into consideration.

6. Urgent conversion to HFA production is needed

For Syria and particularly for the health sector and environment the project is of a very high importance, because the Government of Syria need to urgently convert this company to non-CFC MDI production in order to provide locally produced cheaper MDIs for millions of asthma and COPD patients in Syria, specially those that have low income.

Another urgency to have HFA MDIs available in the country is the absence of imported inhalers in Syria and if they could be even available in the black market they are not affordable for most of Syrian population due to their higher price in comparison with those produced by KC Pharma. The low income of the majority of the people in Syria and in the Middle East region in general and the absence of good health insurance programs in most of the countries of the region characterize the pricing policy of KC Pharma with regard to the MDIs.

7. Number of non CFC MDI and DPI sold or distributed by active ingredients in Syria

An official document issued by the Ministry of Health stating that K.C Pharma is the only producer of MDI in Syria is attached.

According to the MOH's regulation "the Executive Instructions of Medical Drug Importation into Syria" it is stated in paragraph 2 that "…a company or a person cannot import any medicine into Syria if the same medicine is being produced in Syria…"(the MOH website: http://www.moh.gov.sy/arabic/drugs/fmain_13.htm).

However, if the medicine has another pharmaceutical form like, for example, DPI instead of MDI, the MOH allows other form of medicine to be imported.

With regard to import of MDIs or DPIs in Syria that there were only two types of imported inhalers and they were all in the DPI form.

Brand name	***Composition***	***Type***	***Manufacturer***	***Price, US$***	***Qty imported in 2007***
Seretide	Salmeterol 50 mcg Fluticasone 100 mcg 60 inhalations	DPI	GSK	N/A	1000 Pcs
Seretide	Salmeterol 50 mcg Fluticasone 250 mcg 60 inhalations	DPI	GSK	36.5	1000 Pcs

Brand name	***Composition***	***Type***	***Manufacturer***	***Price, US$***	***Qty imported in 2008***
VentolinDiscuss	Salbutamol 200 mcg, 60 inhalations	DPI	GSK	8.15	1500 Pcs

The difference in cost between Ventolin Discuss (Salbutamol 200 mcg), US$ 8.15 being imported by GSK and the similar product Butovent (Salbutamol 100 mcg, 200 inhalations), US$ 2.60 being produced by K.C. Pharma is US$ 5.55. The prices of DPIs from GSK are higher and prices of the similar MDI inhalers from K. C. Pharma are nearly 80% lower proving that it would not be possible to substitute the local MDIs with imported MDIs or DPIs.

There are no more official data available concerning imported CFC MDIs or HFC MDIs in Syria or DPIs as those items are likely sold only in an illegal way because their imports are prohibited in Syria, if locally manufactured and their figures are unknown to authorities but could be relatively small.

8. CFC use in 2008-2010

As the production and sales figures were revealed, the 40 % of the 2007 growth showed that the production and the consumption of CFC was increased dramatically over the last years and especially after KC Pharma entered new markets. Also an increase of population due to Iraqi refugees stipulated the growth of MDI

production at the company. An annual growth in production between 40 to 50 % is further expected in the short time.

9. National Transitional strategy

The present project preparation request is being submitted to enable not only the conversion to the HFA MDI production in Syria but also the smooth transition to
non-CFC MDIs in Syria, therefore phasing out CFC consumption in the MDI sector. In reviewing the data and information submitted, it was noted that there are serious variations in the supply of DPIs and MDIs produced and that the possible imports of CFC or HFA MDIs could be also prone to significant fluctuations. This may result in problems with availability of affordable MDIs that could affect patient care. It is due to the weakness of planning of anti-asthma/COPD medicines imports and because of this it impacts the patient population negatively, therefore there is a need to strengthen the system.

All the MDI products (CFCs and non-CFCs) are presently registered by Drug Administration of the Ministry of Health of Syria. The National strategy should address these tendencies in Syria associated with the increase of number of Asthma and COPD patients and analyze the dynamics of MDI imports and local production.
The National Transition Strategy will take in to account the current management approaches and prescribing habits associated with the treatment of Asthma and COPD in Syria. It will however also be mindful of current international “best practice” thinking associated with the management of those diseases. It will also make analyses of quantities of “reliever” and “preventing” medicines against asthma and COPD.
The national transition strategy will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of Ministry of Health, Drug Administration, health professionals, pharmaceutical companies/ association and the community.

The National Transitional Strategy will be developed as a part of the MDI project for K.C. Pharma.

Venezuela: Request for technical assistance to prepare CFC phase-out project in manufacture of Aerosol Metered Dose Inhalers (MDIs) and MDI transition strategy

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

(i) name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
(ii) type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
(iii) growth patterns of CFC-MDI production over the past five years;
(iv) whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
(v) each production facility's plan for phasing out CFC consumption; and
(vi) the number of non-CFC MDIs and DPIs sold or distributed within the Party, by active ingredient, brand/manufacturer, and source.

On behalf of the Government of Venezuela, UNIDO is submitting a request for preparation of an MDI investment project dealing with the phase-out of 29.56 MT of CFCs at Laboratorios L.O. Oftalmi, C.A. (Calle 6 Zona Industrial La Urbina, Centro Empresarial R.S. Caracas 1070, Venezuela) and a transition strategy to phase-out CFC use in the MDI consumption sector. Data gathered during the NPP implementation showed that Venezuela manufacture about 2.0 million of CFC MDIs as well as import about 2.4 million of CFC and non CFC MDIs and even small quantities of DPIs.

The Table below shows imported CFC-based MDI, CFC-free MDIs and DPIs in Venezuela for the past three years.

CFC MDIs	761300	923000	1007200
DPIs	369700	470200	561400
HFA MDIs	592700	771300	854000
Total	**1723700**	**2164500**	**2422600**

It also showed that the trends of both CFC and non-CFC MDIs imports are increasing. The available data indicates that 1,135,000 units of such medical products were in use in 2005 and this number increased to 1,860,000 units in 2007. The quantity of CFC MDIs prevails on the CFC-free MDIs. There is also an overall concern from the Government of Venezuela and its health authorities on the MDI sub-sector particularly, since the incidences of chronic destructive pulmonary disease (COPD) and asthma are rising, Therefore, there is a need to ensure a steady supply of MDIs to meet these patients' needs. According to the survey conducted in 2003 in the Latin America the asthma prevalence was 7.1% in Venezuela and

this rate was the highest among the Latin American countries (Asthma control in Latin America: the Asthma Insights and Reality in Latin America (AIRLA) survey).

The requested funding for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs in Venezuela. Regulations would also be needed that would promote and support the phase-out of these products, and a programme that would raise physician awareness and patient acceptance of alternatives to CFC-MDIs, as well as monitoring imports of MDIs. In support of their submission and based on decision 51/34, UNIDO indicated that the situation with regards to the manufacturer of MDIs and their non-CFC equivalents imports in Venezuela can be briefly described as follows:

(a) There is the production of CFC-based MDIs in Venezuela by the local producer, i.e. Laboratorios L.O. Oftalmi, C.A. at the actual capacity rate of about 2.0 million MDIs in 2007.

(b) There are CFC MDIs, HFA MDIs and DPIs in the market in Venezuela;

(c) There is a growing share of CFC MDI's in the market in 2005-2007;

(d) The imports of CFC MDIs during 2003-2005 were slowly increasing and imports of CFC MDIs went up to 50 percent of the market in 2007;

(e) Imports of HFA MDIs were also increasing from 2005 till 2007 up to 854,000 units; and

(f) There are also DPIs available in the market and their share is significant.

The objectives of the requested investment project would be to phase-out the use of CFC-11 and CFC -12 in the manufacture of Salbutamol, Beclomethasone Dipropionate and a combination of Salbutamol/ Beclomethasone Dipropionate Aerosol Metered Dose Inhalers (MDIs) at Laboratorios L.O. Oftalmi, C.A., which represents about 80% of the MDI consumption in the social security in Venezuela. In addition the successful completion of implementation of the project would result in the substitution of the Venticort, Salbutamol, Bucomax and Budecort MDIs being currently produced in Venezuela.

The conversion of Oftalmi to non-CFC based MDl products with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population and thus facilitating access to vital medication for millions of people. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Venezuela owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and the environment.

The CFC National Phase out Plan was approved by the 42nd ExCom in April 2004. The NPP will phase out the total CFC demand of 2,032 ODP tones in Venezuela estimated for 2003. The Plan aims at phasing-out all the remaining consumption of Annex A, Group I CFCs in Venezuela over the period of 2004 – 2010 and it will enable the Government of Venezuela to totally phase-out the CFC consumption by January 01, 2010 except the CFC usage chiller servicing. A series of investment, non-investment, and technical support activities are planned to achieve this target in the foam and refrigeration sectors. The relatively low consumption of CFCs for the MDI production of 20.72 ODP tones in 2003 out of 2,032 ODP tones in comparison with a NPP estimate of 16.0 ODP tones in the aerosol and solvent sectors (2003) was not properly addressed.

2. CFC production lines were established and the production capacity of each production line

Laboratorios L.O. Oftalmi, C.A is the only CFC-based MDl producer in Venezuela. The company, with 100% national ownership, was founded in 1985 and it has been producing CFC MDls since 1991. 80% of Oftalmi's production covers the supply to the Venezuelan Health System. The remaining 20 % goes to the free market of the country. Laboratorios L.O. Oftalmi, C.A is a specialized pharmaceutical company established for ophthalmic products.

Laboratorios L.O. Oftalmi, C.A.

Company address:

Laboratorios L.O. Oftalmi, C.A.
Calle 6 Zona Industrial La Urbina, Centro Empresarial R.S. Caracas 1070, Venezuela
Tel: +58-212-2424904 / 2424747 / 2424774 / 2426304 Ext 112
Fax: +58-212-2424424 / 2424656
Website: http://www.oftalmi.com
Owner: Mr. Sebastián Ruscica

To this date Laboratorios L.O. Oftalmi, C.A. is the only manufacturer of Metered Dose Inhalers in Venezuela. The production line for MDI was set in 1991 for one product only. Nowadays the company manufactures six different MDI products, all of which are of high quality. The MDIs, which are being produced by Laboratorios L.O. Oftalmi, C.A. were originally conceived and developed by the Research and Development Department of the company using the pharmaceutical experience of the world-leading MDI producers. All of the MDIs were approved for manufacture and sales in the country by the local sanitary authority "Instituto Nacional de Higiene Rafael Rangel", a department of the Ministry of Health.

Presently there is no licensing agreement and/or technical assistance contract between Laboratorios L.O. Oftalmi, C.A. and any other company.

Since January 1st 2007 there has been no local production of CFC propellants in Venezuela and Laboratorios L.O. Oftalmi, C.A. has had to rely on local suppliers and distributors and their current stock. The company was assured by the Ministry for Environment that this stock would be sufficient to cover 2007 and 2008 at the current consumption levels of Laboratorios L.O. Oftalmi, C.A.

2.1. Type of MDI Products manufactured at Oftalmi

The six MDI products are manufactured at Laboratorios L.O. Oftalmi, C.A. They are:
Venticort, Duovent, Cromospray, Salbutamol, Beclomax and Budecort. Beclomethasone dipropionate is produced in two strength 50 µg and 200 µg. Laboratorios L.O. Oftalmi, C.A. currently consumes both CFC-11 and CFC-12 in the manufacture of aerosol MDIs. The CFC-

11 is used for the preparation of a "slurry suspension " of the active ingredient to facilitate filling the precise quantity into the open aerosol MDI container, after which the MDI aerosol container is closed with the aerosol metering valve, and the CFC-12 that acts as the aerosol "propellant" is injected into the aerosol container under pressure through the metering valve. This production process applies for all CFC aerosol products according to Secretaría de Salud (Mexican Health Agency). Specifications for the following products are:

Commercial Brand	**Generic Name**	**Active per Dose (valve actuation)**	**Total actuation volume (mcl)**	**Total Nº of doses per canisterº**
Venticort	Salbutamol (Albuterol / Beclomethasone dipropionate	100 µg / 50 µg	63	200
Duovent (*)	Fenoterol hydrobromide / Ipratropium bromide	50 µg / 20 µg	63	200
Cromospray (*)	Cromolyn sodium	5 mg	120	112
Salbutamol	Salbutamol (albuterol)	100 µg	63	200
Beclomax	Beclomethasone dipropionate	50 µg	63	200
Budecort	Beclomethasone dipropionate	200 µg	50	100

The MDI manufacturing facilities at Laboratorios L.O. Oftalmi, C.A. are well managed and all production has strict quality control of all stages of the procurement and storage of materials and components, as well as the manufacturing process fully meeting the requirements of the Good Manufacturing Practices (GMPs). This is required for effective medication delivery and use by asthma patients.

2.2. MDI Production Capacity at Oftalmi

The actual capacity of production of Metered Dose inhalers is about 2,000,000 units per year on a basis of 8 working hours per shift, one shift per day, 5 days per week and a total of 225 working days per year. This is an estimated capacity based on company’s past and current production statistics. The installed production capacity is about 5,000,000 units per year. These estimates do not take into account a small research and development line, which has a laboratory scale capacity.

At present time, the customer’s demand is covered with about 2 millions units/year, but in 2008 the demand could be increased due to population growth and governmental social policies.

The details of the MDIs being produced at Oftalmi is given in the table below:

Metered Dose Inhalers manufactured by Oftalmi using CFC propellants

Commercial Brand	Generic Name	Active per Dose (valve actuation)	Total actuation volume (mcl)	Total Nº of doses per canisterº	Propellants
Venticort	Salbutamol (Albuterol / Beclomethasone dipropionate	100 µg / 50 µg	63	200	11, 12
Duovent (*)	Fenoterol hydrobromide / Ipratropium bromide	50 µg / 20 µg	63	200	11, 114
Cromospray (*)	Cromolyn sodium	5 mg	120	112	12, 114
Salbutamol	Salbutamol (albuterol)	100 µg	63	200	11, 12
Beclomax	Beclomethasone dipropionate	50 µg	63	200	11, 12
Budecort	Beclomethasone dipropionate	200 µg	50	100	11, 12

(*) These products were discontinued in May 2004 because of the unavailability of propellant 114. Efforts were made in trying to reformulate the products using combinations of 11 and 12 with no success.

Annual production output per product (in units per year)

Product	2003	2004	2005	2006	2007
Venticort	261.086	363.514	368.640	463.112	785.419
Duovent (*)	63.220	66.910	45.315	0	0
Cromospray (*)	55.949	58.425	8.014	0	0
Salbutamol	596.111	593.054	732.649	555.787	546.296
Beclomax	294.378	325.415	319.616	141.663	423.680
Budecort	281.563	286.112	273.487	147.106	193.622
Totales	**1.552.307**	**1.693.430**	**1.747.721**	**1.307.668**	**1.949.017**

Annual production output (in units)

Year	Total annual production, units
2003	**1.552.307**
2004	**1.693.430**
2005	**1.747.721**
2006	**1.307.668**
2007	**1.949.017**
Total	**8.250.143**

2.3. Manufacturing description and product specifications

The aerosol filling system mainly consists of a mixing/homogenizing vessel, a rotary index based pressure filling machine and a recirculating system for filling a "concentrated mix" (low vapour pressure propellant + active + excipients) and a single piston propellant filling pump.

The mixing vessel (1) has a maximum capacity of about 120 kg and has a double blade rotating agitator (3) with a homogenizing device at the end of its shaft (4). It can provide a maximum of 70 rpm for main agitator and 3600 rpm for homogenizer. Its maximum nominal working pressure is 10 bar but it has attached a safety valve set to 7 bar (2). This vessel has a freon-cooled coiled jacket, which can provide the temperature up to –20ºC to the inner side and also has the capability of working at the room temperature (Manufacturer: ***Greatide Industrial Co., Ltd. 5th Fl. Nº9, Sec 3, Jen Air Road, Taipei 10651***, Taiwan ROC).

The filling machine (8.) is an integrated monobloc rotary index pressure filling machine that has a crimping head and a filling head (***Terco, Inc.459 Camden Drive, Bloomingdale, IL.USA***). This machine is an all-pneumatic driven controlled equipment and it does not have any electrical or electronic component other than conveying system (9). It requires 25,50 cfm@80-100 psi oil-free filtered compressed air.

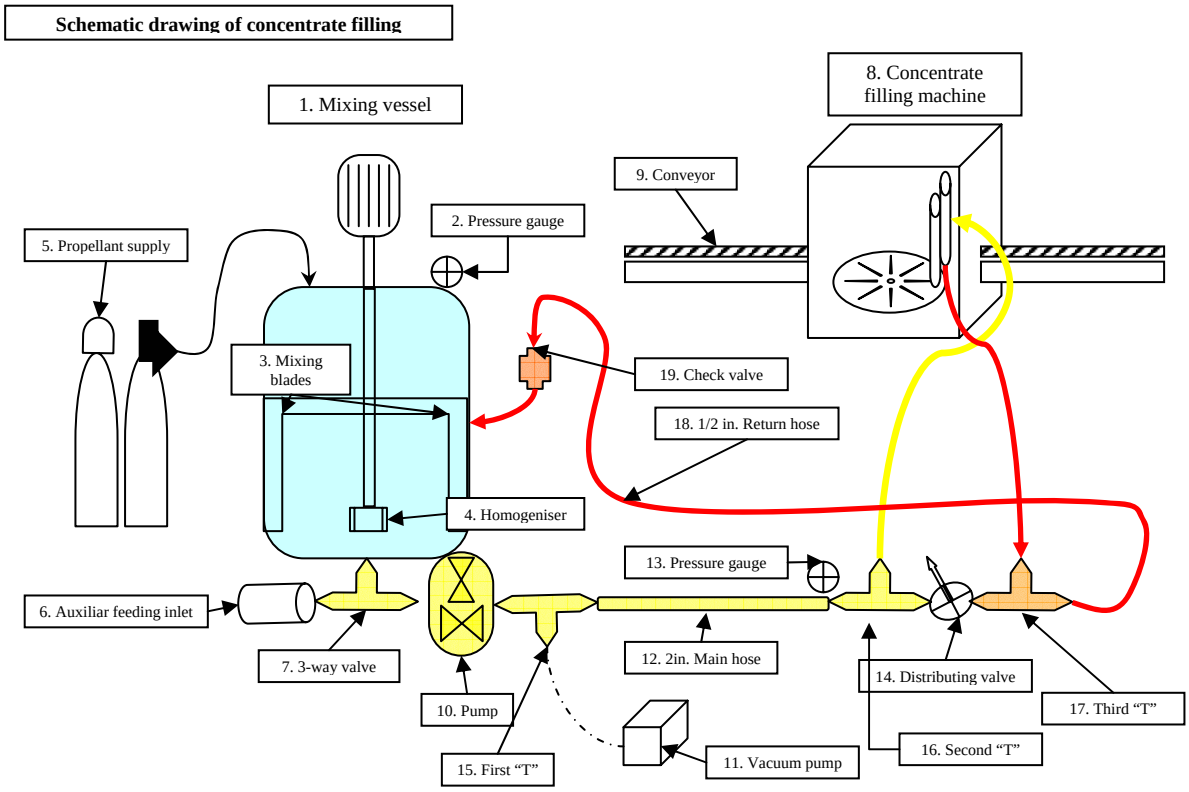
The recirculating system consists of a twin-wing rotary piston pump (10) attached to the bottom of the tank. This pump transfers the mix through a 1 feet long/2 in. i.d. Tygon high-pressure hose (12) to a double T-valve system, which distributes the product to feed the machine or to recirculate it to the tank again.

Pictured in yellow is the outgoing way the concentrate runs through when is pumped away from the tank to the filling machine: there is a 3-way valve (7) attached to the bottom of the tank to allow to feed additional propellant or active adjustments through an auxiliary feeding inlet (6), when the system is pressurized and turned on. Then there is a pump and after that a first "T" (15) with a safety valve through which a vacuum (11) is applied into all the system before turning it on. When the product is running inside the recirculating system it goes through a 2 inches i.d. high-pressure hose to a second "T" (16) where is driven to the filling machine (8) or to the third "T" depending on the situation whether a distributing valve between them is open or closed.

Once the product mix is ready in the mixing vessel a vacuum is applied inside the distributing system, pump (10) is turned on and distributing valve is set to open position; it allows products free run through the whole distribution system and back to the mixing vessel without reaching the filling machine. When the distributing valve is almost fully closed, pressure at point 13 (see a drawing below) reaches 80-120 psi, the product goes to the machine´s feeding inlet hose, machine is turned on, and then the filling process starts.

Between each machine's two strokes the system opens a valve set, which allows the product to go back to the recirculating system and then back to the vessel (pictured in red is the returning path).

This production line is considered as completely unfit for production of HFA MDIs, since construction materials in contact with product and/or propellant are not suitable or compatible. Different working temperatures and pressure ranges also influentiate the expected outcomes.

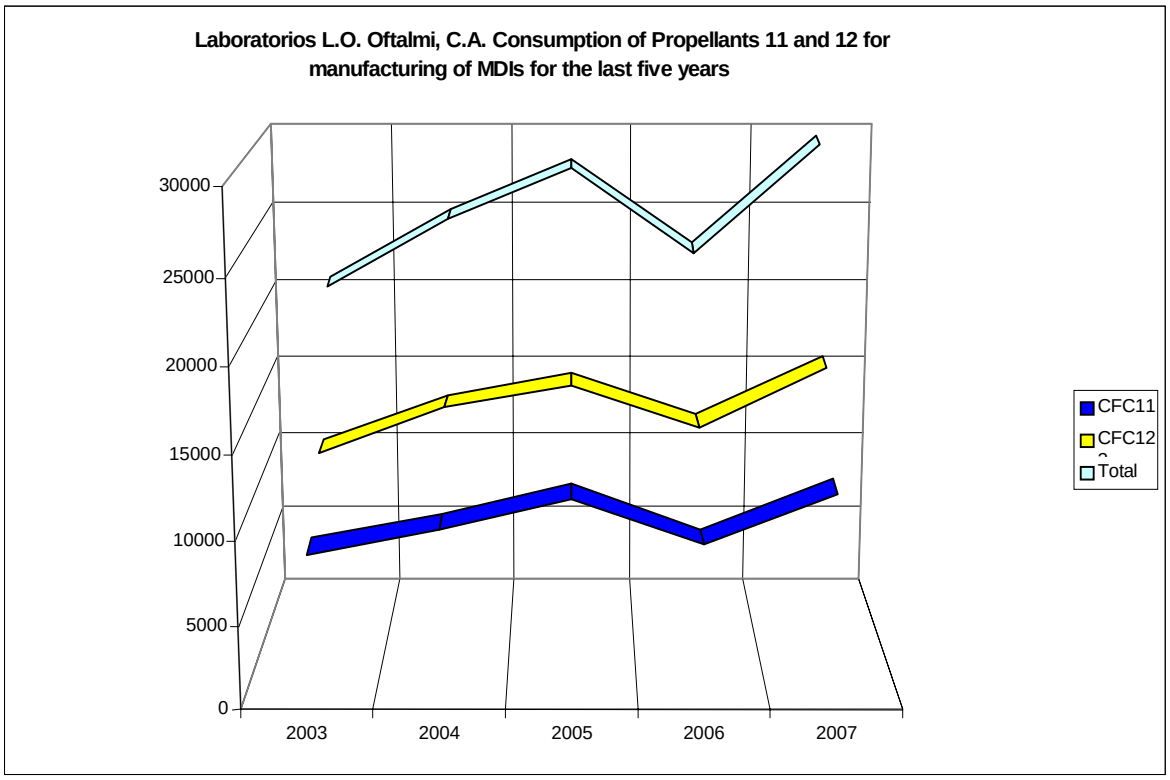


Note: *Numbers are referred to "Schematic drawing of concentrate filling machine" drawing below.*

2.4. Annual Consumption of CFC Propellants used in Manufacturing of MDIs

The next table below displays the consumed quantities of CFC propellants for manufacturing MDIs during the past three years.

Year	***Propellant 11***	***Propellant 12***	***Total consumption of CFCs (in Kg)***
2003	*8450*	*12266*	*20716*
2004	*9904*	*15055*	*24959*
2005	*11714*	*16391*	*28105*
2006	*8989*	*13864*	*22853*
2007	*12106*	*17454*	*29560*
Total	***51163***	***75030***	***105477***
Average	***10232***	***15006***	***26369***



3. Existing Equipment at Oftalmi

The major equipment is:

- mixing/homogenizing vessel
- rotary index based pressure filling machine
- recirculating system for filling a "concentrated mix" (low vapour pressure propellant + active + excipients) and a single piston propellant filling pump.

The mixing vessel has a maximum capacity of about 120 kg and has a double blade rotating agitator with an homogenizing device at the end of its shaft. It can provide a maximum of 70 rpm for main agitator and 3600 rpm for homogenizer. Its maximum nominal working pressure is 10 bar but it has attached a safety valve set to 7 bar. This vessel has a freon-cooled coiled jacket which can provide until –20ºC to the inner side and has the capability of working at room temperature also (Manufacturer: ***Greatide Industrial Co., Ltd. 5th Fl. Nº9, Sec 3, Jen Air Road, Taipei 10651***, Taiwan ROC).

The filling machine is an integrated monobloc rotary index pressure filling machine that has a crimping head and a filling head (***Terco, Inc.459 Camden Drive, Bloomingdale, IL.USA***). This machine is an all-pneumatic driven controlled equipment and it does not have any electrical or electronic component other than a conveying system.

3. New Machinery for HFA products

This paragraph represents a summary of the MDI manufacturing facility that has been designed for use with the HFA formulation. This aerosol MDI manufacturing facility can operate at approximately 40 - 50 cans per minute giving an annual output of about 3 million cans/year based on 230 working days/single shift operation. This was used to determine the

level of capital cost that Laboratorios Oftalmi would need taking into consideration specific requirements.

This machine is capable of filling HFA propellant only or HFA product suspensions or solutions under pressure through the aerosol valve.

Equipment Required: The final list of equipment to produce HFA MDIs including the one currently used for CFC MDI is as follows:

Equipment Required for HFA
1. Mixing Vessel and Macromat Line for Filling MDI with HFA Suspensions/Solutions with Commissioning and installation.
2. Spray Checking Machine.
3. New HFC storage propellant system (15 tons).

Equipment in place or not needed
1. Air Filters.

The following table shows a list of required machinery to be procured and its cost estimate to fulfill the requirements of production of new MDIs using HFA propellants.

Equipment item	**Cost in CHF**
Feeding Plate	1.320,00
Conveyor Belt 6 m	17.890,00
Macromat P 2045 /014 Pharma	114.236,00
Valve inserter P 2058	16.650,00
Vacuum crimper P 2002/021 and Vacuum Pump P14019/004	30.905,00 F
Diagraphm Filler P 2079	44.160,00
Vacuum Pump P14019/004 Type MLD 50 Viton	5.670,00
Double Diagraphm pum P2089/001	41.450,00
Propellant Pump P2008/012	12.350,00
Propellant Filter P 2011/021	33.103,00
Valve Transport System X02047-038	41.040,00
Valve Sorting System Type RNA	38.140,00
Valve Elevator	22.250,00
Checkweigher OCS HC-IS 2000-2	65.510,00
Pressure Mixing Vessel and accesories	205.080,00
Accesories and complements	9.310,00
Packing	2.500,00
FOB European Seaport	5.600,00
Seafreight costs	6.565,00
Insurance	3.300,00
Total Price CIF la Guaira / Venezuela	717.029,00

This equipment is manufactured by:
Pamasol Willi Mäder AG
Driesbüelstrasse 2 Postfach 157

CH-8808 Pfäffikon SZ Switzerland
Tel: +41 (0) 55 417 40 36

Costs associated to legal or regulatory affairs, training, consultancy, marketing, storage and distribution and weight average cost of capital have not been included in estimated figures above.

5. Plan for phasing out CFC consumption in the production facility

5.1. Replacement Technology, HFA formulations and materials

To implement the selected replacement technologies, Laboratorios Oftalmi, will require technology transfer from one, or more, established multinational enterprises that have experience in the manufacture of CFC-Free MDIs using alternative technologies and that have the right to transfer such technology without infringement of any intellectual property related to either the drug molecule, the method of formulation, the design of the metering valve or actuator, or the filling process.

The selected replacement technologies require different production processes than those used at present for the existing CFC-MDI products:

a) Salbutamol HFA-MDI
b) Beclomethasone Dipropionate HFA-MDI
c) Salbutamol/ Beclomethasone Dipropionate HFA-MDI

A. Salbutamol HFC-MDI

For the conversion of Salbutamol CFC-MDI to HFC-MDI based on a suspension of Salbutamol or Salbutamol Sulphate in HFC-134a Laboratorios Oftalmi requires completely different production equipment.

The HFC-134a will replace both CFC-11 and CFC-12 in the CFC-MDI formulation, because HFC-134a is a gas at atmospheric pressure this will involve the preparation of a slurry Salbutamol or Salbutamol Sulphate suspension in HFC-134a in a pressure vessel. Precisely measured amounts of the Salbutamol/HFC-134a "suspension slurry" will then be injected under pressure through a modified metering valve into the already closed aerosol MDI container. A further injection of HFC-134a will be made into the aerosol container through the metering valve to clear any of the Salbutamol/HFC-134a "suspension slurry" from the valve. Also, due the HFC-134a is more abrasive than CFCs, the machine has need different characteristics.

B. Beclomethasone Dipropionate HFC-MDI

Both 50 mcg and 200 mcg doses Beclomethasone Dipropionate MDIs need to be solutions. The medicament drug suspension is manufactured basically by similar technology as used for the CFC MDI version, but the CFC-11 used as the liquid phase of the suspension and to solubilise the surfactant, as well as to modify the final vapour pressure of the MDI formulation, is replaced by ethyl alcohol (ethanol). However, due to the different solubility properties of ethanol and CFC-11 the surfactant has to be replaced by a new surfactant chemical. This suspension is then, metered in the aluminium monobloc container. The propellant CFC-12 is replaced by HFC-134a. As the spray/particle size characteristics of the ethanol/HFC-134a MDI formulation are different to those of the CFC MDI version, the valve

and actuator have to be redesigned to achieve the required spray and particle size characteristics for efficacious dosage. Some products use HFC-227ea as the propellant instead of HFC-134a.

C. **A combination of Salbutamol and Beclamethasone dipropionate** 200 Dose, 100 µg + 50 µg/ dose label claim (or an alternate combination of a Beta agonist and steroid that are acceptable from the perspective of market needs and technology transfer costs).

The combination of Salbutamol and Beclamethasone dipropionate conversion is based on a suspension of combination of Salbutamol and Beclamethasone dipropionate in HFC-134a or HFC-227 or in mixture will replace both CFC-11 and CFC-12 in the CFC-MDI formulation. The process will involve the preparation of a slurry drug suspension in HFC propellant in a pressure vessel. Precisely measured amounts of the combination of Salbutamol and Beclamethasone dipropionate /HFC propellant will be injected under pressure through a modified metering valve into the already closed aerosol MDI container. A further injection of HFC will be made into the aerosol container through the metering valve to clear any of the combination of Salbutamol and Beclamethasone dipropionate suspension from the valve.

At present time there are not licensing, technical assistance, or technology transfer agreements relating to HFC-MDI manufacture.

For the CFC conversion projects the retrofit of existing CFC manufacturing equipment is not possible because of the poor compatibility of the HFC-134a or HFC-227 with existing machinery seals and because of the new preparation and method of filling. As a result, completely new CFC-free MDI manufacturing facilities are required.

The transition process from CFC-MDIs to CFC-free MDIs in Laboratorios Oftalmi requires that for a period of some time there will a need for production of both CFC-MDIs, and CFC-free MDIs. The transition process will be carried on in two steps: first to convert Salbutamol CFC-MDI aerosol suspension to a CFC-free MDI aerosol suspension. In the second step, Beclomethasone Dipropionate and combination of Salbutamol and Beclamethasone dipropionate will be converted and the rest of CFC will be eliminated.

5.2. Project duration period

After Project approval for Salbutamol (First step)

• Plant adaptation and equipment installation and product test: 11 months.
• Product Registration to produce in Venezuela: 3 months.
• Starting production at commercial level: 1 month.

For Beclometasone plus certifications and reports (Second step) 6 months more for:

• Product Registration to produce in Venezuela: 3 months
• Starting production at commercial level: 1 month.
• Verifications certifications and reports: 2 months.

For Salbutamol/Beclometasone (mixture) plus certifications and reports (Third step) 6 months more for:

• Product Registration to produce in Venezuela: 3 months

• Starting production at commercial level: 1 month.
• Verifications certifications and reports: 2 months.

Preliminary estimation for the project duration is 3 years.

5.3. Urgent conversion to HFA MDI production is needed

For Venezuela, and particularly for the Ministry of Environment this project is of a very high importance, because the Government of Venezuela needs to urgently achieve conversion of CFC MDI to non-CFC MDI production in order to provide cheaper MDIs for millions of asthma and pulmonary disease patients in Venezuela, especially those with a low income.

Asthma is a public health problem and a well-recognized urban chronic respiratory disease in Venezuela. Acute asthma ranks second in morbidity after the "viral syndrome" and ahead of diarrhea and other diseases with more than a million acute asthma crises per at the Ministry of Health ambulatory services. This network system attends to the majority (70-80% or more) of a predominant young and urban – around 80% -population (24 million inhabitants; 40% under 15 years of age) living in crowded urban dwellings in variable conditions of poverty. On other hand a shortage of specialized asthma clinics across the country rounds up a focused and prevailing general approach centered on acute care. The International Study for Asthma and Allergies in Children (ISAAC) Venezuela 2003 informs of nearly one million urban persistent asthmatics (6-13 years of age) and hence the need for long-term anti-inflammatory medications. There is an overall concern from health authorities in Venezuela about the MDI supply, since the prevalence of chronic destructive pulmonary disease (COPD) and asthma is rising.

6. Transition Strategy for the elimination MDIs with CFCs and the introduction of the replacement CFC MDIs in Venezuela

6.1. Number of non-CFC MDI and DPI sold or distributed by active ingredient, brand/manufacturer, and source

The Table below shows the quantities of CFC and non-CFC MDIs as well as DPIs imported into the country by active ingredient, brand/manufacturer, and generic name in the past three years.

Quantities of CFC and non-CFC MDIs and DPIs imported into the country

Brand name	Manufacturer	Drug	Class	Generic name	2005	2006	2007
FORADIL	NOVARTIS	Formoterol	R03A3	DPI	88000	106000	111300
FLUIR	VALMORCA		R03A3	DPI		5100	12400
SEREVENT	GLAXO SMITH KLINE	Salmeterol	R03A3	HFA	4900	4600	4100
FORMOTEC	PHARMACEUTICAL GROUP	Formoterol	R03A3	HFA		500	1100
SALBUTAN	GLAXO SMITH KLINE	Salbutamol	R03A4	HFA	205000	261900	412000
SALBUROL	VALMORCA	Salbutamol	R03A4	HFA	94600	143800	138500
SALBUTAMOL	L.O.	Salbutamol	R03A5	HFA	142600	154300	
SALBUMED	MEDIFARM	Salbutamol	R03A4	HFA		11500	74400

ASTHALIN HFA	PHARMACEUTICAL GROUP	Salbutamol	R03A4	CFC		51800	109600
ASTHALIN ECO	PHARMACEUTICAL GROUP	Salbutamol	R03A4	HFA		20100	
SALBUTAMOL	MEDIFARM	Salbutamol	R03A4	CFC	23800	1300	
BUDECORT	L.O.	Budesonide	R03D1	CFC	19000	33700	41500
PULMICORT TURBOHALER	ASTRA ZENECA	Budesonide	R03D1	DPI	92600	95200	109900
PULMICORT AERO	ASTRA ZENECA	Budesonide	R03D1	HFA	56100	60900	75100
ALVESCO	GRUNENTAL	Ciclesonide	R03D1	CFC		8500	21800
MIFLONIDE	NOVARTIS	-	R03D1	DPI	18400	22200	26200
BUDESONIDA	MEDIFARM	Budesonide	R03D1	CFC	20400	32400	40900
ASMANEX	SCHERING P.	Mometasone	R03D1	DPI	1700	9300	9100
PULMOLET	LETI	Budesonide	R03D1	CFC	4000	11700	10600
FLIXOTIDE	GLAXO SMITH KLINE	Fluticasone	R03D1	HFA	4900	4000	6200
BECLOSIL	MEDIFARM	Beclamethasone	R03D1	CFC	4500	6500	
BECLOFORTIL	MEDIFARM	Beclamethasone	R03D1	CFC	1800	1900	1800
SYCORT	PHARMACEUTICAL GROUP	Ciclesonide	R03D1	HFA		100	2600
SERETIDE	GLAXO SMITH KLINE	Salmeterol+ Fluticasone	R03F1	DPI	31200	38700	48600
SERETIDE	GLAXO SMITH KLINE	Salmeterol+Fluticasone	R03F1	HFA	83300	94300	105600
VENTIDE	GLAXO SMITH KLINE	Salbutamol+ Beclamesone	R03F1	CFC	387600	415200	360200
FORASEQ	NOVARTIS	Formoterol	R03F1	DPI	42600	56500	73800
SYMBICORT	ASTRA ZENECA	Budesonide+ Formetorol	R03F1	DPI	83800	100500	115500
VENTICORT	L.O.	Salbutamol	R03F1	CFC	111500	135800	171400
BUTOSOL	MEDIFARM	Beclamethasone	R03F1	CFC	25700	37200	48900
AEROCORT	PHARMACEUTICAL GROUP	Beclamethasone	R03F1	HFA		13500	28600
BECLOMET	VALMORCA	Beclamethasone	R03F1	CFC	100	7200	14200
SEROFLO	PHARMACEUTICAL GROUP	Salmeterol+Fluticosone	R03F1	HFA			2700
FORACORT	PHARMACEUTICAL GROUP	Salmeterol+ Budesonide	R03F1	HFA			3100
BERODUAL	BOERINGER ING	Ipratropium Bromide+Fenoterol	R03G4	CFC	149400	167800	174500
COMBIVENT	BOERINGER ING	Ipratropium Bromide + Salbutamol	R03G4	CFC	13500	12000	11800

SPIRIVA	BOERINGER ING	Tiotropium Bromide	R03G3	DPI	11400	36700	54600
ALOVENT	BOERINGER ING	-	R03G4	HFA	1300	1800	
TOTAL					**1723700**	**2164500**	**2422600**

Annual CFC- MDIs, non-CFC MDIs and DPI production				
Propellant	2005		2006	2007
CFC	761300		923000	1007200
DPI	369700		470200	561400
HFA	592700		771300	854000
Total	**1723700**		**2164500**	**2422600**

Both CFC and non-CFC MDIs imports are increasing in Venezuela. 1,135,000 units of such medical products were in use in 2005 and this number increased to 1,860,000 units in 2007. The quantity of CFC MDIs is still above CFC-free MDIs.

6.2. National Transitional Strategy

The national transition strategy as a part of the MDI conversion project will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of the Ministry of Health, physicians, health professionals, pharmaceutical companies/association and the community.

The education and sensitising campaign for the introduction of new products (HFA MDIs) will therefore be both necessary and challenging in this situation. Considering the above-mentioned elements the implementation of an education programme involving health professionals, patients, their families and the community from the very beginning becomes a priority, led by the Ministry of Health and Medical Education.

PTC/MEA/VS
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