United Nations Development Programme

Dear Mr. Abid Ali,

19 January 20

Phase –out of CFC Consumption in the Manufacture of Metered Dose Inhalers (MDIs) In Pakistan

I am pleased to share with you the Project Document for the project titled, "Phase- out of CFC Consumption in the Manufacture of Metered Dose Inhalers in Pakistan" signed by UNDP.

The Multilateral Fund Secretariat approved funding for 4 years (2009- 2011) at a cost of US $ 449,996. Ozone Cell, Ministry of Environment, Government of Pakistan, is the implementing partner for the project. In sharing the enclosed project document, we would request to sign the project document .The document is to be signed between the Ministry of Environment and UNDP.

We take this opportunity to reiterate our commitment to the Government of Pakistan to meet the national environmental challenges and look forward to the successful implementation of the project.

With best regards,

Yours Sincerely,

Munazza Naqvi
Officer In-charge/Programme Officer
Energy & Environment Unit

Mr. Abid Ali,
Joint Secretary (IC) /
NPD Montreal Protocol -IV
Ministry of Environment
Government of Pakistan
Islamabad

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SIGNATURE PAGE

Country: **Pakistan**

UNDAF Outcome(s)/Indicator(s): *(Link to UNDAF outcome. If no UNDAF, leave blank)*	Key UN Conventions promoted; capacity improved to fulfill their obligations
Expected Outcome(s)/Indicator (s):	Phase-out the consumption of 91.2 ODP tones of CFC 11 and CFC 12used in the manufacture of Metered Dose Inhalers (MDIs) in Pakistan by 2011
Expected Output(s)/Indicator(s): *(CP outcomes linked to the SRF/MYFF goal and service line)*	
Implementing partner: *(Designated institution/Executing agency)*	Department of Environment of the Ministry of Environment and Forests
Other Partners:	

Programme Period:	2009-2011
Programme Component:	Sector Phase-out of CFC consumption in Manufacture
Project Title:	Phase-out of CFC consumption in the Manufacture of Metered Dose Inhalers (MDIs) In Pakistan
Project ID:	00059141
Award ID:	00073862
Project Duration:	48 Months

Total budget:	USD 449,996
Allocated resources:	
• Government	
• Regular	
• Other:	
o Donor	MLF
• In kind contributions	

Agreed by (Government): _____ 1/2/2010

Agreed by (UNDP): _____

Toshihiro Tanaka
Country Director
United Nations Development Programme
Islamabad, Pakistan

19-01-10

UNDP Project Document

UNDP – MLF

Government of Pakistan

In collaboration with

United Nations Development Programme

PAK/ARS/56/INV/71 – Phase-out of CFC consumption in the Manufacture of Metered Dose Inhalers (MDIs) in Pakistan

The objective of this project is to phase-out the consumption of 91.1 ODP Tonnes of CFC 11 and CFC 12 used in the manufacture of Metered Dose Inhalers (MDIs) in Pakistan by 2012. To be able to achieve this goal, the Multilateral Fund is providing assistance to the two local manufacturers of MDIs in Pakistan to convert the production form using CFC to using HFA 134a. The assistance provided will comprise technical assistance and the provision of equipment.

The project will be executed by the Government of Pakistan in collaboration with UNDP.

This project will be executed in parallel with the Transition Strategy for the phase out of CFC MDIs in Pakistan. The Transition Strategy has been prepared by the Government of Pakistan in collaboration with the United Nations Environment Programme and is separately funded and will be implemented by UNEP

The project will be implemented over a period of 3 years beginning in June 2009. The total budget of the project is US$449,996 and will be funded by the MLF.

The grant requested to the MLF by the Government of Pakistan is US$ 449,996

Starting Date – June 2009

Total Budget - US$ 449,996

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ACRONYMS

CFC	Chlorofluorocarbon
CPAP	UNDP Country Program Action Plan
HCFC	Hydrochlorofluorocarbon
HFC	Hydro fluorocarbon
HFA	Hydro fluoroalkane
IA	Implementing Agency
MDI	Metered Dose Inhaler
MLF	Multilateral Fund
NOU	National Ozone Unit
ODP	Ozone Depleting Potential
ODS	Ozone Depleting Substances
TPMP	Terminal Phase-Out Management Plan
UNEP	United Nations Environment Programme
UNDP	United Nations Development Programme

PART I: Situation Analysis

Pakistan ratified the Vienna Convention and Montreal Protocol in 1992. The status of ratification of Montreal Protocol and its amendments by Pakistan is given in the table below.

Amendment	Ratification Date
Vienna Convention	18th December 1992
Montreal Protocol	18th December 1992
London Amendment	18th December 1992
Copenhagen Amendment	17th December 1995
Montreal Amendment	10th February 2005
Beijing Amendment	10th February 2005

Source: Ozone Secretariat

Pakistan prepared its Country Program in 1993, which was updated in 2002. Pakistan has an Institutional Strengthening Project which commenced in 1994. Pakistan has had a number of phaseout and technical assistance projects in the refrigeration, solvents, fumigants, foams and halon sectors; to help it achieve its phase out targets of ODS in these sectors.

The consumption of ODS in Pakistan over the last five years is given in the table below.

Chemical Class	2003	2004	2005	2006	2007	Baseline
CFCs	1,124.00	805.00	453.00	626.00	170.27	1,679.40
Halons	15.00	7.20	0.00	0.00	0.00	14.20
Other Fully Halogenated CFCs	0.00	0.00	0.00	0.00	0.00	0.00
Carbon Tetrachloride	589.10	752.40	148.50	41.80	0.00	412.90
Methyl Chloroform	0.00	0.00	0.00	0.00	0.00	2.30
HCFCs	58.20	14.00	5.30	65.50	183.69	
HBFCs	0.00	0.00	0.00	0.00	0.00	
Bromochloromethane	0.00	0.00	0.00	0.00	0.00	
Methyl Bromide	0.00	0.00	0.00	0.00	0.00	14.00

Source: Article 7 data reports submitted to the Ozone Secretariat.

Consumption trends in Annex A Group I substances

In Pakistan, CFCs – which are listed under Annex A Group I substances - are typically consumed in refrigeration and air-conditioning applications, foam applications and aerosol applications including MDIs. Pakistan does not produce CFCs and is dependent on import of CFCs from countries like India, China and developed countries producing CFCs for basic domestic needs of Article 5 countries. With dwindling CFC demand as a result of CFC consumption phaseout activities which also includes CFC MDI phaseout, the supply of pharmaceutical grade CFC's for MDI manufacture will continue to be constrained in the coming years.

2.2 Consumption of CFCs in MDIs in Pakistan and Usage Patterns

There are currently three locally based manufacturers of MDI in Pakistan, GSK Pakistan Limited which has a 21% local shareholding and Macter Pharmaceutical which has 100% local ownership. The MDI products produced in Pakistan are CFC based and currently, there is no local capacity or capability to produce non-CFC based MDIs in the country.

The Consumption of CFC in the MDI manufacturing Sector in Pakistan in the year 2007 was approximately 99.57 MT of CFC 12 and 11 accounting for a local production of 4.21 million units. The data for the last six years is presented below:

Year	Number of Units	Quantity of R11 (MT)	Quantity of R12 (MT)
2002	2 701 518	20.38	44.27
2003	2 556 277	19.23	41.77
2004	2 923 177	26.51	59.98
2005	2 165 912	25.14	56.78
2006	3 584 611	26.03	58.71
2007	4 211 934	18.37	81.20

There is no export of the locally produced MDIs in Pakistan.

According to the Asthma Insights and Reality Survey done in Pakistan in 2005, it is estimated that about 5% of the Pakistani population have asthma. Based on the current population, this would mean that there is an estimated 8 million people suffering from asthma in Pakistan. Complete details of the data from this study are presented as the appendix 1.

Based on the local manufacturing capacity, only a percentage of the population can be supplied with MDIs. However, as the use of the drugs become more widespread in the rural areas of Pakistan and as a result of greater awareness among the population of the ease of use of asthma and COPD drugs in the MDI form, the demand for the MDIs will increase. As a result of this, it is expected that local manufacturing of MDIs will significantly increase in order to meet the growing demand. In view of the present manufacturing capability, this will mean an increase in the demand for pharma grade CFCs. While there is importation of the MDI drugs using CFC and HFA, the cost of the imported drugs are higher (with the exception of drugs imported from China which are also CFC based and will therefore be ultimately unavailable) than the locally produced drugs making their affordability and ultimate off-take into the market lower than locally produced MDIs and restricted to higher income groups. This higher cost of imported drugs coupled with the market demand may explain the establishment of a new CFC MDI manufacturer – Macter. For formulations not produced in Pakistan, these will be continued to be imported, but in the absence of the guidance of a transition strategy along with a conversion project that will help to create conditions to establish such bans and change the direction that the market is taking, it will be difficult to prevent the introduction of other CFC MDI formulations since the technology is readily available.

2.3 Industry structure for MDIs in Pakistan

There are three manufacturing Companies in Pakistan:

- GlaxoSmithKline Pakistan Limited – 79% multinational shareholding, 21% Pakistani shareholding
- Macter International (Pvt) Limited – 100% Pakistani Shareholding
- ZAFA Pharmaceutical Laboratories Ltd – 100% Pakistani Shareholding

2.4 MDI manufacturing industry in Pakistan

Pakistan has 3 companies producing CFC MDIs.

Basic information on the production facilities manufacturing CFC MDIs is given in the table below.

Name of Facility	Date of Establishment of MDI Production Lines (equipment installation)	Date of First Production	No. of CFC Production lines	Production capacity per annum
GlaxoSmithKline Pakistan Limited	1981	1981	1	4M
Macter International (Pvt) Limited	1994	2007	1	10M

ZA . Pharmaceutical Laboratories Ltd	1998	1996	1	.2M

GSK currently produces the majority of CFC MDIs in Pakistan accounting for over 90% of the production in 2007. As Macter has now started production in the end of 2007, it is expected that that 2008 can see a significant jump in the consumption of CFCs, given that the capacity of the Macter facility can produce up to 10 million units per year. Zafa accounts for the smallest production in Pakistan.

PART II: Strategy

Project objective

To Phase out the use of CFC in the manufacture of MDIs in GSK Pakistan and Zafa International

This objective will be achieved through the provision of incentive payments to GSK for partial funding for phase out of CFC MDI Salbutamol and funding for technical assistance for the development of Salbutamol in HFA and equipment replacement for Zafa Pharmaceuticals as outlined below:

Zafa: Equipment to be Replaced/Retrofitted

Aerosol filling machine
Aerosol capping machine
Aerosol gassing machine
Manufacturing tank
And other ancillaries (piping, chillers, dehumidifier etc.)

Total Cost to Fund – USD 196,000

Zafa: Technical Assistance for Development of Salbutamol

Total Cost to be funded – USD 80,500

GSK:

Incentive payment to be divided into three equal payments as follows:

On Project Signature – 33.3%
On Procurement of Formulation – 33.3%
On Launch of Product – 33.3%

Total Cost – USD 123, 496

PART III: Management Arrangements

This Project will be executed under the NEX modality and will be executed by the National Ozone Unit of Pakistan which falls under the purview of the Department of Environment, Ministry of Environment and Forests.

To assist the Government of Pakistan to manage this project an international expert will be hired by UNDP to carry out the following tasks:

- Develop TORs for Technical Assistance and Equipment

Conduct Technical evaluation of all bids for Technical Assistance and Equipment
- Act as Liaison between Technology and Equipment supplier and the Government of Pakistan/UNDP
- Verify project deliverables are met
- Preparation of Project Completion Report
- Any other task as required by the Government of Pakistan/UNDP

The Government of Pakistan as executing agency will be required to provide the following services:

These services include, but are not limited to the following:

- Preparation of all TORs for consultants hired under this project
- All tendering and hiring of goods and services
- All annual progress reports
- Ensuring all targets are met

UNDP as implementing agency will be responsible for:

- Ensuring performance and financial verification in accordance with specific UNDP and Multilateral Fund procedures, rules and regulations;
- Providing verification to the Executive Committee that the consumption targets and the activities as stated in this project document have been met as per schedule;
- Assisting the Government of Pakistan in preparation of yearly implementation progress reports;
- Ensuring that technical reviews undertaken by UNDP are carried out by appropriate independent technical experts, including the designation of an independent expert when required to verify that payment milestones have been achieved;
- Carrying out required supervision missions to monitor the delivery of the services included in this Project Document to the designated beneficiary;
- Ensuring the presence of an operating mechanism to allow effective, transparent implementation of the project, and accurate data reporting;
- Ensuring that disbursements/compensation payments are made to Government, technology supplier and equipment and material suppliers on agreed terms upon receipt of invoices which are properly substantiated;
- Providing assistance with policy when required;
- Providing independent technical supervision missions and certifies completion of the project;
- Providing a copy of the Project Document, letter confirming UNDP role as paying agent to the Government of Pakistan and the technology provider:

SECTION II: STRATEGIC RESULTS FRAMEWORK

Phase-out of CFCs as per the MP commitments and availability of sustainable treatment for asthma/COPD patients

SECTION III: TOTAL BUDGET AND WORKPLAN

Country: Pakistan
Business Unit: PAK10
Short Title: PAK/ARS/56/INV/71
Long Title: Phase-out of CFC consumption in the Manufacture of Metered Dose Inhalers (MDIs) In Pakistan
Total Budget: USD 449,996

Outcome/ATLAS Activity	Responsible Party/ Implementing Agent	Fund	Donor	ATLAS Budgetary Account Code	ATLAS Budget Description	Amount 2009 (USD)	Amount 20010 (USD)	Total (USD)
Activity 1 Technical Assistance for Overall Project Implementation	UNDP/MPU	63030	10009	71200	International Consultants	25,000	25,000	50,000
Activity 2 Product Development, including Technical Assistance and Procurement of Services for Zafa	National Ozone Unit	63030	10009	72100	Contracting Service/ Product Development	80,500	-	80,500
Activity 3 Equipment for Conversion of Production Lines at Zafa	National Ozone Unit	63030	10009	72200	Equipment	98,000	98,000	196,000
Activity 4 Incentive Payment to GSK	National Ozone Unit	63030	10009	72600	Grants	61,748	61,748	123,496