PROJECT IDENTIFICATION FORM (PIF) [1]
PROJECT TYPE: Full-sized Project
TYPE OF TRUST FUND:GEF Trust Fund

PART I: PROJECT IDENTIFICATION

Project Title:	Phase-out of CFC consumption in the manufacture of aerosol metered-dose inhalers (MDIs) in the Russian Federation		
Country(ies):	The Russian Federation	GEF Project ID:[2]	
GEF Agency(ies):	UNIDO (select) (select)	GEF Agency Project ID:	XX/RUS/10/X01
Other Executing Partner(s):	Ministry of Natural Resources and Environment	Submission Date:	2010-09-16
GEF Focal Area (s):	Ozone Depletion Substances	Project Duration(Months)	24
Name of parent program (if applicable): ➢ For SFM/REDD+ ☐		Agency Fee:	250,000

A. FOCAL AREA STRATEGY FRAMEWORK[3]:

Focal Area Objectives	Expected FA Outcomes	Expected FA Outputs	Indicative Financing from relevant TF (GEF/LDCF/SCCF) ($)	Indicative Cofinancing ($)
(select) CHEM-2	Outcome 2.2	241 MT	2,500,000	5,500,000
(select) (select)				
(select) (select)				
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(select) (select)				
(select) (select)				
(select) (select)				
(select) (select)				
(select) (select)				
(select) (select)				
(select) (select)	Others			
Project management cost[4]			50,000	50,000
Total project costs			2,550,000	5,550,000

[1] It is very important to consult the PIF preparation guidelines when completing this template.
[2] Project ID number will be assigned by GEFSEC.
[3] Refer to the reference attached on the Focal Area Results Framework when filling up the table in item A.
[4] GEF will finance management cost that is solely linked to GEF financing of the project.

B. PROJECT FRAMEWORK

Project Objective: The objectives of this project are (a) through appropriate technology transfer, to phase-out the consumption of 241.1 ODP tones of CFC-11 and CFC- 12 used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation (RF) and (b) to manage the transition from CFC-based MDIs to CFC-free MDIs in the country. The primary objective is the direct phase out of 241.1 ODP tonnes of CFCs (2009) in the medical aerosol sector in the Russian Federation. The secondary objective is to reduce future GHG emissions by approx. 2.0 MMT CO2 t/equivalent, by introducing, through technology transfer a lower GHG propellant, HFC-134a. The two MDI companies in the RF will require technology transfer from one, or more, established multinational enterprises that have experience in the development and manufacture of MDIs using CFC-free technologies, and who have the right to transfer such technology to the Russian Federation (RF) 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 within the domestic market. This proposal addresses the requirements for conversion of a manufacturing facility currently using CFCs to manufacture MDIs to one only using HFC-134a.

Project Component	Grant Type (TA/INV)	Expected Outcomes	Expected Outputs	Indicative Financing from relevant TF (GEF/LDCF/SCCF) ($)	Indicative Cofinancing ($)
1. Institutional and regulatory capacity building for ODS phase out in the RF by converting CFC-based MDI production to HFA - based MDI	TA	1.1. Policies reviewed and CFC legislation improved, if necessary. 1.2. Up-grading of ODS and CFC import/export legislation	1.1 Analysis of the level of residual demand of CFC after 2010 and by looking at the stock of ODS in the country made; 1.2. Training of customs officers done and procurement of ODS control equipment for customs made 1.3. Stakeholder (two MDI producers and CFC supplier) framework developed and commitments agreed; 1.4. Improved awareness, educational information and environmental management systems upgraded 1.5 At least two centralized training symposia to train representatives from the Ministry of Health conducted	50,000	100,000

			1.6. Changes to the legislation that ban the import of CFC-MDIs		
2. Phase out of CFC consumption - 241 MT in the Medical Aerosol (MDI) sector at the two Russian enterprises	Inv	2.1.Technical assessment of production capacity within the MDI sector 2.2. Phase out of 241.1 ODP tonnes CFC (CFC-11 and CFC-12)	2.1.Two aerosol filling lines at Federal State Enterprise «MosChimPharm Preparaty» and two lines with two indexing machines at Altayvitaminy installed 2.2. Guidance of the Russian experts on the MVP - Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ of new equipment carried out 2.3. Overall project management incorporating both the elements of MDI design and development and supervision of equipment installation executed 2.4. Assistance (new MDI-Salbutamol production, engineering services, equipment and instrumentation, etc.) required for conduction of three pilot batches provided by technology provider 2.5. Three experimental batches of a new MDI (1500 pcs) together with a	2,300,000	4,700,000

			reference placebo batch (minimum placebo 500 MDIs) carried out at the two enterprises 2.6. Pilot production of CFC free MDI Salbutamol 200 dose, 100 µg/ dose label claim of Salbutamol Base (equivalent) carried out and terminal phase out of CFC consumption in the MDI sector and reduction of GHG emissions achieved		
3.Technology transfer for developing a new HFA-based MDI	Inv	3. Design and developmnet of a new MDI product	3.1.Design and development of a new HFA-based MDI-Salbutamol made by a technology provider including the drug formula, selection of MDI materials and components and transfer of all possible know-how needed to start manufacturing and testing of new MDIs 3.2. All materials and primary packaging components (valve, canister and actuator), of the MDI product excluding the secondary packaging components (carton, package insert etc.) designed 3.3 Final conversion of CFC based MDI Salbutamol 200	100,000	500,000

			dose, 100 µg/ dose label claim of Salbutamol Base (equivalent) (may be formulated using Salbutamol Sulphate and/ or specified in an acceptable manner as the Dose ex mouthpiece achieved		
4. New developed MDI registration by the Ministry of Health	TA	Conduction of stability and clinical tests of the new MDI for the Ministry of Health	4.1. 2 or 3 key events [pilot production, stability tests of new MDI] in the Working Plans of the companies 4.2. 2 or 3 key events [testing results from the local labs, MDI registration] in the Working Plans of the Ministries 4.3. Assessment of stability and clinical tests results 4.3. Final regisraion of a new MDI product	50,000	200,000
	(select)				
	(select)				
	(select)				
	(select)				
	(select)				
	(select)				
Project management Cost[5]				50,000	50,000
Total project costs				2,550,000	5,550,000

C. INDICATIVE CO-FINANCING FOR THE PROJECT BY SOURCE AND BY NAME IF AVAILABLE, ($)

Sources of Cofinancing for baseline project	Name of Cofinancier	Type of Cofinancing	Amount ($)
National Government		Unknown at this stage	
GEF Agency	UNIDO	Grant	50,000
Private Sector	Two Pharamceutical companies in the RF: MosChimPharmPreparaty, Moscow and Altayvitaminy Ltd., Biysk	In-kind	5,500,000

[5] Same as footnote #3.

(select)		(select)	
(select)		(select)	
(select)		(select)	
(select)		(select)	
(select)		(select)	
(select)		(select)	
(select)		(select)	
Total Cofinancing			5,550,000

D. GEF/LDCF/SCCF RESOURCES REQUESTED BY AGENCY, FOCAL AREA AND COUNTRY[1]

GEF Agency	Type of Trust Fund	Focal area	Country name/Global	Project amount (a)	Agency Fee (b)[2]	Total c=a+b
UNIDO	GEF TF	Ozone Depletion Substances	The Russian Federation	2,550,000	250,000	2,800,000
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
(select)	(select)	(select)				0
Total Grant Resources				2,550,000	250,000	2,800,000

[1] In case of a single focal area, single country, single GEF Agency project, and single trust fund project, no need to provide information for this table

[2] Please indicate fees related to this project.

PART II: PROJECT JUSTIFICATION

A. DESCRIPTION OF THE CONSISTENCY OF THE PROJECT WITH:

A.1.1. THE GEF FOCAL AREA STRATEGIES AND OBJECTIVES

The proposed project is consistent with GEF FA Objective CHEM-2: "Phase out of Ozone Depleting Substances (ODS)", Outcome 2.2 "Ozone Depleting Substances", Output 2.2.1 is 241 MT of CFCs.

A.1.2. FOR PROJECTS FUNDED FROM LDCF/SCCF: THE LDCF/SCCF ELIGIBILITY CRITERIA AND PRIORITIES: n/a

A.2. NATIONAL STRATEGIES AND PLANS OR REPORTS AND ASSESSMENTS UNDER RELEVANT CONVENTIONS, IF APPLICABLE, I.E. NAPAS, NAPS, NBSAPS, NATIONAL COMMUNICATIONS, TNAS, NIPS, PRSPS, NPFE, ETC.:

A position paper summarizing the Russian Country Program and phase-out strategy has been prepared by the Ministry of Environmental Protection and Natural Resources (MEPNR) and was submitted to the May 1995 meeting of the Parties to the Montreal Protocol (the Parties). This Country Program has since been formally adopted by the Government with the issuing of a Government Resolution that provides a legal basis for its implementation. While considered in compliance with the control measures of the MP in 1995, Russia has acknowledged that it will be in a non-compliance position beginning in 1996 and has conveyed its commitment to ODS phase-out as set out in the Country program to the Secretariat of the Vienna Convention and Montreal Protocol. It has also resumed formal reporting of ODS consumption, production and trade as required under its obligations to the MP. At the November 1995 meeting of the Parties, Russia agreed to provide additional information relating to the country's political commitment, implementation progress, and enforcement measures, particularly in regard to trade regulations. An agreement was also reached between Russia and the Parties on issues associated with exports. Russia's export of ODS to other supply dependent countries in the FSU after January, 1996 would be accommodated on a transitional basis, conditional on it also taking the necessary action to ensure no re-export takes place from these countries. Russia has agreed to comply fully with the overall export ban requirements of the MP to other countries.

The Russian Federation, in its capacity as the legal successor to the former USSR in respect of the international obligations flowing from the Vienna Convention on Protection of the Ozone Layer (1985), the Montreal Protocol on Substances that Deplete the Ozone Layer (1987) and the London Amendment and adjustments to the Montreal Protocol (1990), was under an obligation to phase out the production of ozone-depleting substances (ODS) by 1 January 1996 and also to fulfill a number of other obligations associated with the phase-out of ODS in the consumption sector.

In compliance with the decisions adopted by the Government of the Russian Federation in 1999 and 2000, the production of substances listed in Annexes A and B to the Montreal Protocol (including CFC-11 and CFC-12) was fully phased out on 20 December 2000. However, the Russian Federation has required CFCs for the production of metered-dose inhalers (MDIs) to meet patient demand. Technical assistance is now required to convert the production of CFC metered-dose inhalers (MDIs) to ozone-friendly HFC - 134a at the two local MDI enterprises. According to the National Plan of Action to Phase-out of Ozone - Depleting Substances in the Manufacture of MDIs over the Period 2005-2007 (2004) the total phase-out of CFCs in the MDI sector in the Russian Federation as planned to be achieved in 2008. However, this task has not yet been fulfilled because funds were not available at the time to assist in this conversion.

A project entitled "Russia Ozone Depleting Substance Consumption Phase-out Project" was established in 1996 with a total budget estimated at US$ 104 million, comprising US$ 60 million grant from Global Environmental Facility (GEF) to be supplemented by US$ 44.3 million from enterprise contribution.

The origin of the Project was the international community's recognition of the difficulty that the

Countries with Economies in Transition (CEITs) in Eastern Europe and the Former Soviet Union (FSU) would have in meeting their obligations under the 1990 London Amendment to the Montreal Protocol (MP), namely the elimination of Annex A and B Ozone Depleting Substances (ODS) consumption and production by December 31, 2000. As non-article 5 countries under the MP they were not eligible for international assistance available under the Montreal Protocol Multilateral Fund (MPF). As a consequence, the Global Environmental Facility (GEF) formally opened an Ozone Focal Area in 1995 for CEITs, who had Country Programs endorsed by the Parties to the MP and had ratified the London Amendment. The World Bank (WB) was a key participant in the development of the Ozone Focal Area starting in 1992, which coincided with an initial project concept being developed for assistance to the Russian Federation. However, the preparation of an actual project could not be completed until GEF Operational Strategy including the Ozone Focal Area was adopted and bilateral programs supporting the Country Program development were completed.

At a general level, the Project's original objectives were adequately defined what the Project was intended to accomplish within the context of international and national priorities at the time. However, unlike GEF initiatives in other CEITs, this Project was not intended to be a comprehensive country phase out in that it was initially limited to phase out investment in only two high consumption sectors (aerosol and refrigeration equipment). As a result of the implementation of the ODS phase out programme CFC production ceased in 2000 in the Russian Federation and further import of Essential-Use CFCs for MDI production is being now regulated on the basis of the annual quota from the Ministry of Natural Resources (MNR) or supplied from the stockpile. Russia has been importing ODSs from China and India since 2003.

It became evident that the CFC phase out programme in the Russian Federation had not included the technical assistance in phasing out CFCs in the production of Metered-dose Inhalers (MDIs) in the country. MDIs are being presently produced by the two Russian enterprises, i.e. «Altayvitaminy Ltd. », Altay region and Federal State Enterprise «MosChimPharmPreparaty», Moscow. These two MDI producers are still consuming annually about 240 MT of CFC-11 (solvent) and CFC-12 (propellant) for the production of the asthma rescue medicine Salbutamol.
This project is consistent with the country's priorities and is designed to terminal phase out of CFCs in the RF by 2012.

B. PROJECT OVERVIEW:

B.1. DESCRIBE THE BASELINE PROJECT AND THE PROBLEM THAT IT SEEKS TO ADDRESS:

Three producers of medical aerosols continue to operate, i.e. Federal State Enterprise «MosChimPharmPreparaty», «Altayvitaminy Ltd.» and «ICN- October Ltd.» and were reported to consume 450 MT of CFC-11/12 mixture in 2000, of which between 300 and 350 MT was for Metered Dose Inhaler (MDI) products. This is estimated to have increased to 516 MT in 2001, «Altayvitaminy Ltd.» is currently implementing an HAP/mechanical pump conversion sub-project in the Project's third tranche, for its non pulmonary (i.e throat sprays and nasal) products, but all three enterprises have elected to continue ODS use for MDI on the basis that they will be granted an essential use exemption under an application currently being made by the Russian Federation. It is most probable that, these enterprises will likely have to close MDI production when access to and/or affordability of banked material no longer exists. After 2005, it was assumed that these producers would converted MDI production to non-ODS technology or ceased production." «ICN- October Ltd.» ceased the production of MDIs, however as there is still a critical market need, the two other enterprises, i.e. Federal State Enterprise «MosChimPharmPreparaty» and «Altayvitaminy Ltd. continue the use of CFCs for production of MDIs with total consumption of 286 MT of CFCs in 2008 and about 290 MT in 2009. Both enterprises have applied for Essential Use Nomination (EUN) for CFCs in order to ensure the supply of pharmaceutical-grade CFCs for the aerosol Metered-Dose Inhaler (MDI) applications after 31st December 2009.
From communication and interaction with both MDI producing companies it is clear that to achieve transition from CFCs in a realistic timeframe they both need technical and monetary assistance in

converting their CFC-based MDI filling lines to MDI production with a non CFC propellant. Further they will require some form of technical input if they are to develop products and processes that also meet the objectives of the Russian Federation of eliminating ODS and manufacturing pharmaceutical products in line with the requirements of Good Manufacturing Practices. Both companies have indicated a desire to select UNIDO as an Implementing Agency (IA) for rendering such assistance and both companies have made statements that they do not have sufficient funds to make the conversion on their own.
Based on the knowledge gained from the companies so far, it is anticipated that a programme, which can see the transition fully from CFC to HFA MDIs, could be implemented within the ultimate timeframe of availability of CFCs. If Russia does not submit an essential use nomination for CFC propellant for MDIs in 2010 for 2011 this will mean that no new CFC will be available in Russia for the manufacture of MDIs. If there is no current stock-pile of pharmaceutical grade CFCs then this potentially represents the premature cessation of manufacture of CFC MDIs in Russia. If at that time manufacture of a HFA replacement is not viable then this either means a chronic shortage of Salbutamol MDI (the primary emergency rescue medication used by Asthmatics) in the Russian market (placing patients at risk) or a massive cost burden associated with increased imports of MDIs, or a combination of the two.

Primarily two Russian enterprises supply Salbutamol to the Russian market, the balance being supplied by imported product. Domestic manufacture accounts for 79% of the volume of the Russian market but only 58% of the dollar value. The remaining 21% of imported product accounts only for 42% of the percentage value of the market. This relationship in the period from 2004 to 2007 is shown in the table below.

Federal State Enterprise «MosChimPharmPreparaty» and Altayvitaminy obtain CFC-11 and CFC-12. These CFCs are used by companies exclusively for the manufacture of Salbutamol sprays.

The Table below shows the production of Salbutamol MDIs by two Russian enterprises in 2006-2010*.

Producer	2006	2007	2008	2009	2010 (expected)
	Number of cans	Number of cans	Number of cans	Number of cans	Number of cans
Federal State Enterprise «MosChimPharmPreparaty»	7,817,082	6,936,000	6,643,000	7,337,000	6,500,000
Altayvitaminy	9,964,000	6,240,000	6,743,000	5,512,000	5,500,000
Total	17,781,082	13,176,000	13,386,000	12,849,000	12,000,000

*Source: Figures were presented in the TEAP meting in Moscow at the Ministry of Health in February 2010.

The cost/ price for the domestic produced MDI was $2.00 per unit and the imported cost of an equivalent MDI in the region was $5.45.

MDI Production	**2004**	**2005**	**2006**	**2007**
Domestic, US$ in million	17.93	12.05	17.78	13.17
Imported, US$ in million	9.28	21.77	21.91	15.30
Total, US$	**27.22**	**33,82**	**39.69**	**28.47**

If the ratios of Domestic vs Imported manufacture are used and a Model cost for the Manufacture of Domestic ($2.00) and Imported ($6.00) are used. This translates in to a market for Salbutamol valued in the region of $30 million.

Production of Salbutamol at the Federal State Enterprise «MosChimPharmPreparaty»*

Year	Salbutamol MDI in cans
2000	3 742 203
2001	4 310 904
2002	4 576 650
2003	4 959 396
2004	6 624 696
2005	5 724 885
2006	7 817 082
2007	6,936,000
2008	6,643,000
2009	7,337,000
2010	6,500,000

Consumption of CFCs at the Federal State Enterprise «MosChimPharmPreparaty»*

Preparation	ODS	2005	2006	2007	2008	2009	2010 (expected)
Kameton, in MT	CFC-12	124,4	81,4	93,1	0		
Salbutamol, in MT	CFC-11	43,0	58,9	25.56	24,4	27,54	21.2
Salbutamol, in MT	CFC-12	77,6	105,5	102,24	97,6	110,16	84,8
Total, in MT		245,0	245,8	220,9	122,0	137.7	106,0

Production of Salbutamol and CFC consumption at Altayvitaminy*

Salbutamol	2003	2004	2005	2006	2007	2008	2009	2010
Production in thousands units	6.898	7.750	7.339	9.994	6.240	6.743	5.512	5.650
CFC-11, MT	9.84	44.0	38.2	48.56	44.0	49.52	41.36	44.24
CFC-12, MT	59.76	66.0	57.3	72.84	66.0	74.28	62.04	61.76
Total, MT	99.6	110	95.5	121.4	110	123.8	103.4	106.0

*Source: Figures were presented in the TEAP meting in Moscow at the Ministry of Health by «Altayvitaminy» and Federal State Enterprise «MosChimPharmPreparaty» in February 2010.

This Project is the GEF funding operation for complete CFC phase-out in Russia. It targets priority ODS consumption phase-out activities in the medical aerosol sector, along with the provision of a technical assistance at the government and enterprise levels. It is structured as a framework project for a total GEF grant which amounts to US$ 2.5 million. The co-finance from the two sub-projects, i.e. Federal State Enterprise «MosChimPharmPreparaty», «Altayvitaminy Ltd.» is US$ 5.5 million of local contribution. The framework Project will be processed in one tranche as funds are approved by the GEF Council. Upon approval of the Project UNIDO will proceed with equipment procurement for the two companies according to the rules and regulations of UNIDO. Also a tender will be conducted by UNIDO (in parallel with equipment procurement) concerning the technology transfer.

Component 1. Technical Assistance will strengthen Russian institutional capacity for ODS Phase-Out, and provide implementation support for the Project's investment activities.
The technical assistance component of the Project has been allocated a total funding of US$ 0.1 million. Efforts should be made jointly by the Ministry of Health of the RF, healthcare providers, physicians, pharmacists and nursing staff and all sectors linked to Health. All these parties should understand that the

transition is not optional and that, over the next few years, all patients currently using CFC products will have to change to CFC-free devices. They should be prepared to help patients to understand the reasons for the change and assist them during the transition.

Patients should be reassured that:
- The new inhalers are as safe and as effective as the previous ones.
- CFCs are damaging to the global environment but not damaging to the health of the individual.
Although the patients may observe minor differences in appearance, dosage and taste, these do not imply any reduction in the effectiveness of the medicines.
- Appropriate visual and written educational materials should be developed to foster this process and media should be used for their dissemination. Mass media can and must play a fundamental role in raising awareness. In the RF, easy and broad access to mass media is available to public.
Education is a continuous process, a partnership between professionals and patients that involves an exchange of information and adequate opportunity for patients to express their fears and concerns. Although physicians are the patients' first source of information on medications, they do consult also other physicians, pharmacists and other information sources when they have questions about the treatment of asthma. It is therefore crucial that all these parties have the same information and give consistent advice to patients. With adequate preparation and reinforcement of the key messages, the transition can be completed successfully.
All importers applicable will be formally contacted in writing by MOH and given details of the phase out programme for CFC MDIs and advised of their obligations to remove any such products from the Russian market.
Encourage importers of inhalation products to support the patient awareness/ education program.
Importers of inhalation products will be contacted directly to review what current and future resources they can make available.
Develop an educational training package.
With the support of external agencies where possible to develop an integrated package of materials, (printed, recorded etc.) for the purpose of training primary, secondary and tertiary training staff.
Plan and execute at least two centralized training symposia to train representatives.
It is not practical to disseminate the key messages to all individuals with direct patient interaction, in a single communication event. It is more practical to train selected individuals and provide them with materials to; in turn train key personnel at a more regional level. Two top level training symposia will be planned.
Roll out of training initiatives
Support will be given at a local level to facilitate workshops, symposia, printed material, to ensure that the individuals trained in the primary sessions can distribute the key messages to all primary patient contacts. For the following years several local and regional workshops should be planned for information sharing, and elaboration and discussion of the guidelines to be approved, where the transition to CFC-free MDIs will be included in the National Programme of Asthma and COPD.
Suitable awareness enhancing media (posters, leaflets etc.)
Where appropriate to produce supporting materials for direct patient awareness.

Component 2. Phase Out of CFCs at the two pharmaceutical companies. This project is designed to achieve this reduction in two phase out sub-projects in the biggest CFC consuming industries to deliver a directly funded phase out of 241.1 MT of CFCs through a) provision of the new HFA-based filling lines for the two enterprises and b) provision of technology transfer from one, or more, established multinational enterprises that have experience in the development and manufacture of MDIs using CFC-free technologies. The cost of four manufacturing lines based on a single Aerosol Pharma Filling Line Type Macromat is US$ 2.0 million plus additional 0.5 million is needed to equip the two filling lines with two automatic packing machines only for Federal State Enterprise «MosChimPharmPreparaty», which are available in the baseline equipment. Although the theoretical capacity of each Macromat is 30 - 40 cans/minute (depending as on the volume and valve to be filled) as the line output is determined by the rate of the check-weigher and manual loading/ unloading and the batch sizes are set by the vessels. In order to

achieve similar outputs and efficiencies to the current CFC installed capability, the effective new output as described above will be around 60 cans per minute for Altayvitaminy working in one shift per day and MosChimPharmPreparaty working in two shifts per day.

Component 3. Technology Transfer. The technology supplier must provide support to the two companies in the RF to give an alternative manufacturing capability to the existing CFC-MDI facility. The technology should have access to Salbutamol/Salbutamol sulphate HFC-MDI. The technology provider should be able to provide assistance in the following ways:

• Access to data in support of regulatory approval
• Dossier compilation including product development
• Facility design and equipment installation qualification
• Training in any new analytical methods, which may be required.
• Recommendations on sourcing of components
• Recommendations on facility and equipment validation
• Assistance in the production of a determined number of batches of Salbutamol in presence of the two companies technicians.
• Control checks to comply with the established quality standard.
• Compilation of the final verification report to identify that the new product has been successfully transferred.
The cost for technology transfer is estimated at the level of US$ 0.5 million.

B. 2. **INCREMENTAL /ADDITIONAL COST REASONING**: describe the incremental (GEF Trust Fund) or additional (LDCF/SCCF) activities requested for GEF/LDCF/SCCF financing and the associated global environmental benefits (GEF Trust Fund) or associated adaptation benefits (LDCF/SCCF) to be delivered by the project:

The Russian Federation has demonstrated a significant commitment to the elimination of the use of Ozone Depleting Substances (ODS) in a number of industrial sectors. With the assistance of significant grants from the Global Environmental Facility (GEF) CFC manufacture has ceased in Russia and the use of CFC has been dramatically reduced. However the issues associated with the use of CFCs in MDIs were effectively deferred. It became evident that without some intervention in the form of financial assistance, it is most probable that the MDI projects would either continue to slip, or that the enterprises may be placed in a position where they have to consider ceasing manufacture of MDIs, as they are no longer commercially viable or the approved materials (CFCs) are no longer available. A number of reasons for the slippage in the programme for the development of HFAs have been cited, including
- Lack of funding from the procurement of equipment required to develop the new MDI formulations.
- Lack of funding for the procurement of new industrial scale equipment to produce stability batches etc. This equipment will also facilitate the adoption of GMP ways of working with respect to MDI manufacture.
- Significant personnel changes within the two companies that resulted in the loss of continuity and experience.
- A general lack of experience relating to the demands of developing a new type of a MDI with HFC-134a propellant (an HFA MD).
- Competing priorities for limited resources. The resources in place have commitments to existing production, manufacturing systems improvement e.g. Good Manufacturing Practices (GMP) and product development.

The Government of the RF has requested UNIDO in 2009 to provide technical assistance to the two enterprises in converting CFC-based production of the MDIs into CFC-free one. UNIDO has been involved in the MDI conversion since 2006 when the first UNIDO project in the MDI sector was approved for Egypt. Then it was followed by the projects in China, Mexico and Iran. A project is urgently needed by the both companies to be equipped with new CFC-free equipment, which allows the use of

HCF-134a propellant in the MDI production. The RF, moreover, applied to the Meeting of the Parties of the Montreal Protocol in 2009 and 2010 for Essential Use Nomination of CFCs for the MDI production in 2010-2011.

B.3. DESCRIBE THE SOCIOECONOMIC BENEFITS TO BE DELIVERED BY THE PROJECT AT THE NATIONAL AND LOCAL LEVELS, INCLUDING CONSIDERATION OF GENDER DIMENSIONS, AND HOW THESE WILL SUPPORT THE ACHIEVEMENT OF GLOBAL ENVIRONMENT BENEFITS(GEF TRUST FUND) OR ADAPTATION BENEFITS (LDCF/SCCF). AS A BACKGROUND INFORMATION, READ MAINSTREAMING GENDER AT THE GEF.":

As the global phase out of CFC in pharmaceutical MDIs is increasingly implemented the countries associated with scale manufacture of pharmaceutical grade CFCs will disappear and there is an expectation of very significant increases in the costs of CFC propellants in the future. As in a typical Salbutamol the propellant may account for 30 – 40% of the total cost of the MDI, then any increase in the cost of propellant will impact on the cost of the MDI. Therefore, any further delay with this project may have a negative impact on the costs of provision of medicine and hence Russian patients.
It is clearly identified that on unit by unit basis the cost of an imported MDI product is far greater than that of a domestically produced item. Using a very conservative cost difference estimate of $2.00 per MDI and if all the domestically produced MDIs in the Russian Federation were replaced with imported equivalents, then as a minimum the impact on the cost of provision of MDIs at the current level would be US$30 million, as mentioned on page 6, bearing in mind that the total number of MDIs manufactured in the Russian Federation may exceed 15 million cans. This would either result in additional pressure on public and private funding of medicine or would result in a decrease in the number of patients with access to essential medication.

This project, if implemented would achieve the total phase out of CFCs in the Russian Federation. The project will provide the direct phase-out of 241 ODP MT (2009) in the medical sector and reduce future GHG emissions by approximately 2.0 MMT CO2e.

B.4 INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS THAT MIGHT PREVENT THE PROJECT OBJECTIVES FROM BEING ACHIEVED, AND IF POSSIBLE, PROPOSE MEASURES THAT ADDRESS THESE RISKS TO BE FURTHER DEVELOPED DURING THE PROJECT DESIGN:
Assuming that the enterprises manufacturing CFC MDIs receive no financial assistance and as a result find it too commercially challenging to convert their products to HFA MDIs in the shorter term or at any point, then there are a number of potential risks, which may be envisioned.

There is already a significant increase in the cost of pharmaceutical grade CFC propellant worldwide. As the global phase out of CFC in pharmaceutical MDIs is reduced the economies associated with scale manufacture will disappear and there is an expectation of very significant increases in the costs of CFC propellants in the future. As in a typical Salbutamol the propellant may account for 30-40% of the total cost of the MDI, then any increase in the cost of propellant will impact in the cost of the MDI.

Further by becoming totally dependant on an import based strategy for MDIs to support Russian patients. The logistics, supply chain and buffer stock issues mean that the risk of potential shortage within the national distribution chain will carry significantly higher levels of risk. The result of this would be patients who are dependant on the regular availability of essential medication, may be placed at risk. As the global phase out of CFC in pharmaceutical MDIs is reduced it is widely acknowledged that management of the supply of pharmaceutical grade CFC will be via very rigidly administered essential use nomination allowances. This will lead to significant limits on the availability of CFCs and no ability for companies to increase production to meet potentially increasing market needs. In the event that manufacture of MDIs ceased in the Russian Federation, then there is a current demand for MDIs in the region of 15 million per annum. If Russian patients are not to suffer shortages of essential medication then

this quantity would need to be sourced from international companies. 15 million per annum is a significant quantity and may well exceed the current "spare" manufacturing capacity of the companies who may be interested in importing products into Russia.

Of equal importance to cost and availability of the medication to the patient is quality. In some circumstances an MDI may be a life saving medicine. As a result it is absolutely essential that any patient can rely on the quality and efficacy of the product in their hand. This is clearly recognized in the Russian Federation as is evidenced by the programme for the implementation of GMP.

It is evident that there is an increasing demand for MDIs in the Russian Federation, the prohibitive costs associated with an import only strategy may result in significant pressure to extend the period of essential use nomination (and hence use of CFC), so as not to endanger the lives of asthmatic patients. The potential market pressures that may result from lack of affordable MDIs, increases the opportunity for the ever increasing problems of counterfeiting occurring in the pharmaceutical industry. There is a risk that such counterfeit MDIs may be manufactured from illegal or sub standard stocks of CFCs, continuing the use of CFCs and exposing the patients to significant health risks.

The project must consider installing or upgrading the lab equipment to make sure both have adequate facilities for monitoring the quality of the HFA MDIs are available. The stability tests to be conducted at the both enterprises would demand some specific test equipment, which need to be procured or rented by the two Beneficiaries.

No climate change related risk. Any quantity of CFCs in the stock will be incinerated. Transportation to the dismantling facilities will be done following the requirements for safe handling CFCs being considered as toxic chemicals. These measures will minimize the risk.

B.5. IDENTIFY KEY STAKEHOLDERS INVOLVED IN THE PROJECT INCLUDING THE PRIVATE SECTOR, CIVIL SOCIETY ORGANIZATIONS, LOCAL AND INDIGENOUS COMMUNITIES, AND THEIR RESPECTIVE ROLES, AS APPLICABLE:

The Ministry of Health and Social Development; the Federal Service for Health Supervision (Roszdravnadzoz); the Ministry of Natural Resources and Environment will be the principle national counterparts of the project. The Ministry of Health and Social Development will be involved in developing/modification any regulations on the use of CFCs in the production and importation of MDIs. It will be also responsible for final MDI product registration after assessment of the results of stability and clinical tests to be conducted by the own lab of the Ministry. It will be also responsible for establishing requirements and stimulus for the two enterprises to implement the Montreal Protocol Agreement.

B.6. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES:

Decision XXI/4(8) of the MOP requested the Technology and Economic Assessment Panel and its Medical Technical Options Committee of the Montreal Protocol Fund to "organize and undertake a mission of experts to examine the technical, economic and administrative issues affecting the transition from CFC metered dose inhalers to CFC-free alternatives in the Russian Federation, and to report the results of this mission to the meeting of the thirtieth Open-ended Working Group. The Technology and Economic Assessment Panel is requested to examine:

(a) The status of transition in the enterprises manufacturing CFC MDIs;

(b) Technical, financial, logistical, administrative or other barriers to transition;

(c) Possible options to overcome any barriers and facilitate the transition."

Experts for the Russian Federation mission team were selected by the co-chairs of the Medical Technical Options Committee (MTOC) in consultation with the Technology and Economic Assessment Panel (TEAP). Funding for the mission was provided by the Ozone Secretariat via grants provided by the Governments of Sweden and Finland, and the two enterprises of the Russian Federation manufacturing CFC MDIs.

The TEAP/MTOC team visited the Russian Federation during 8-12 February 2010 at the invitation of the Ministry of Health and Social Development, which coordinated a number of meetings. The team met with a range of experts from the Russian Federation including: the Ministry of Health and Social Development; the Federal Service for Health Supervision (Roszdravnadzoz); the Ministry of Natural Resources and Environment; the State Federal Unitary Enterprise "Federal Centre of Geoecological Systems"; the Ministry of Industry and Trade; the two Russian Federation enterprises manufacturing CFC MDIs (JSC Moschimpharmpreparaty and JSC Altayvitaminy); the Russian Federation enterprise that imports pharmaceutical-grade CFCs (JSC Phyton).

As a conclusion of the mission was the necessity of urgent project.financing. Since finance governs the success of the transition in the Russian Federation, financial support is the main priority. GEF funding should be investigated urgently as the first option. Based on the TEAP/MTOC mission, the Parties could expect that 24 months would be the overall time for conversion of the two enterprises once funding is approved by the implementing agency.

C. DESCRIBE THE GEF AGENCY'S COMPARATIVE ADVANTAGE TO IMPLEMENT THIS PROJECT:

THE GEF agency (UNIDO) is within the comparative advantage matrix.

C.1 INDICATE THE CO-FINANCING AMOUNT THE GEF AGENCY IS BRINGING TO THE PROJECT:

UNIDO will bring the amount of US$ 50,000 for formulation of the full-scale project. It would finance the detailed scoping and design of the pilot project covered by the FSP document. Through detailed development of the pilot project concepts, plans, budgets and operating models the necessary inputs, outcomes and outputs required to achieve the project objectives will be optimized. It will also allow the development of the logical framework and indicators to effectively monitor the implementation process and it will ensure that the resources provided under the FSP achieve the greatest possible impact.

C.2 HOW DOES THE PROJECT FIT INTO THE GEF AGENCY'S PROGRAM (REFLECTED IN DOCUMENTS SUCH AS UNDAF, CAS, ETC.) AND STAFF CAPACITY IN THE COUNTRY TO FOLLOW UP PROJECT IMPLEMENTATION:

At initial stage, the project will create and initiate training of a project team at the two Russian enterprises to run project activities during the mature phases of the project. UNIDO is also planning at the very beginning to organize a meeting of all stack holders to see the project goals from different angles, especially the analyses of the local market for MDIs and imports of foreign MDIs into the country.

The combination of the legislation/incentives created during the project life, successful implementation of the domestic legislation, lack of CFC and other accumulated experience and skill would permit the project teams to achieve the total phase out of CFCs in the production of the MDIs in the Russian Federation.

PART III: APPROVAL/ENDORSEMENT BY GEF OPERATIONAL FOCAL POINT(S) AND GEF AGENCY(IES)

A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT (S) ON BEHALF OF THE GOVERNMENT(S): (Please attach the Operational Focal Point endorsement letter(s) with this template. For SGP, use this OFP endorsement letter).

NAME	POSITION	MINISTRY	DATE *(MM/dd/yyyy)*
Dr. Igor Maydanov	Deputy Minister	MINISTRY OF NATURAL RESOURCES AND ECOLOGY	**07/07/2010**

B. GEF AGENCY(IES) CERTIFICATION

This request has been prepared in accordance with GEF/LDCF/SCCF policies and procedures and meets the GEF/LDCF/SCCF criteria for project identification and preparation.					
Agency Coordinator, Agency name	**Signature**	**DATE** *(MM/dd/yyyy)*	**Project Contact Person**	**Telephone**	**Email Address**
Dr. Dmitri Piskounov Managing Director of UNIDO		15/09/2010	Mr. Viktar Shatrauka	43-1-26026-4578	V.Shatrauka@unido.org