INDEPENDENT EVALUATION DIVISION
OFFICE OF EVALUATION AND INTERNAL OVERSIGHT

Independent Terminal Evaluation

Phase-out of CFC consumption in the manufacture of Aerosol Metered Dose Inhalers (MDIs) in the Russian Federation

UNIDO Project ID.: 100352
GEF Project ID.: 4387

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List of acronyms and abbreviations

AWP	Annual Work Plan
BAT	Best Available Techniques
BEP	Best Environmental Practices
CFC	Chlorofluorocarbons
CoP	Conference of the Parties
EA	Enabling Activities
ET	Evaluation Team
GEF	Global Environmental Facility
HFC	Hydrofluorocarbons
ISID	Inclusive and Sustainable Industrial Development
MDI	Metered-dose Inhalers
MNRE	Ministry of Natural Resources and the Environment
MoP	Meeting of the Parties
MTOC	Medical Technical Options Committee of TEAP
ODG/EVA	UNIDO Office for Independent Evaluation
ODS	Ozone-depleting Substances
OECD/DAC	Organization for Economic Cooperation and Development/Development Assistance Committee
PIR	Project Implementation Report
PM	Project Manager
PMU	Project Management Unit
PSC	Project Steering Committee
RBM	Results-based Management
RF	Russian Federation
TE	Terminal Evaluation
TEAP	Technology and Economic Assessment Panel of Montreal Protocol
ToC	Theory of Change
ToR	Terms of Reference
UNEG	United Nations Evaluation Group
UNIDO	United Nations Industrial Development Organization

Glossary of evaluation-related terms

Term	Definition
Baseline	The situation, prior to an intervention, against which progress can be assessed.
Effect	Intended or unintended change due directly or indirectly to an intervention.
Effectiveness	The extent to which the development intervention's objectives were achieved, or are expected to be achieved.
Efficiency	A measure of how economically resources/inputs (funds, expertise, time, etc.) are converted to results.
Impact	Positive and negative, intended and non-intended, directly and indirectly, long term effects produced by a development intervention.
Indicator	Quantitative or qualitative factors that provide a means to measure the changes caused by an intervention.
Lesson Learned	Generalizations based on evaluation experiences that abstract from the specific circumstances to broader situations.
Logframe (logical framework approach)	Management tool used to facilitate the planning, implementation and evaluation of an intervention. It involves identifying strategic elements (activities, outputs, outcome, impact) and their causal relationships, indicators, and assumptions that may affect success or failure. Based on RBM (results-based management) principles.
Outcome	The likely or achieved (short-term and/or medium-term) effects of an intervention's outputs.
Outputs	The products, capital goods and services that result from an intervention; may also include changes resulting from the intervention which are relevant to the achievement of outcomes.
Relevance	The extent to which the objectives of an intervention are consistent with beneficiaries' requirements, country needs, global priorities and partners' and donor's policies.
Risks	Factors, normally outside the scope of an intervention, which may affect the achievement of an intervention's objectives.
Sustainability	The continuation of benefits from an intervention, after the development assistance has been completed.
Target groups	The specific individuals or organizations for whose benefit an intervention is undertaken.
Theory of Change	The way of describing the project that focuses on the sequences of intended results and associated assumptions.

Executive summary

The project *Phase-out of CFC consumption in the manufacture of aerosol metered dose inhalers (MDIs) in the Russian Federation,* funded by the Global Environment Facility (GEF) was implemented from March 2012 to March 2018 by the United Nations Industrial Development Organization (UNIDO). The main national partners of the project were the Ministry of Natural Resources and Environment (MNRE), and two factories that produced CFC-containing Salbutamol MDI. The project had the following financing sources: GEF: USD 2,550,000; co-financing (cash and in kind): beneficiary companies USD 5,600,000; UNIDO: USD 100,000; Total: USD 8,150,000.

The project has two main objectives*:* (a) through appropriate technology transfer, to phase-out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation; and (b) to reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer, a lower GHG propellant.

This project is Highly Relevant as it supports the compliance of RF with the Montreal Protocol (MP) obligation of phasing out production and consumption of CFCs, while providing the required technical assistance to convert the production of CFC-based metered-dose inhalers (MDIs) to ozone-friendly HFC-134a at the two national companies producing Salbutamol MDI, a lifesaving drug. The proposed project is consistent with GEF Focal Area Objective CHEM-2: "Phase out of Ozone Depleting Substances (ODS)", Outcome 2.2 "Ozone Depleting Substances", Output 2.2.1 is 212 MT of CFCs.

The project received substantial co-financing from the benefiting companies, which is in line with GEF's additionally or so-called incremental approach principles. The GEF incremental funding enabled technology transfer that speeded up the process of developing and obtaining approvals for a CFC-free MDI replacement, contributing to the RF's compliance with the Montreal Protocol obligation of total phase out of CFC consumption, without impacting the availability of MDI Salbutamol in the RF market.

Effectiveness of the project is considered **Moderately Satisfactory**. The two companies have installed the production lines and have already produced and sold the new formulation of Salbutamol MDIs. This means that both companies installed the production lines and prepared the necessary infrastructure for the lines to operate (works had to be performed in the rooms containing the lines and adjacent rooms), and both have successfully passed the Site Acceptance Test (SAT). This also means that the new Salbutamol formulations have been developed and registered. The RF has stopped proving quotas for imports of CFCs since 2015, and no more CFC containing Salbutamol MDIs are being produced. The objective of the project will be achieved when the two plants start mass-producing the new CFC-free Salbutamol MDI.

Efficiency is rated **Moderately Unsatisfactory.** The project started in January 2012, and was initially planned to be completed within 24 months (December 2014). However, only in October 2017 the project finally came to an end with the last activities completed. Besides, not all results were achieved within the original budget. The two purchase orders to equipment supplier PAMASOL amounted to USD

2,521,395, using all GEF grant and cutting-off part of the UNIDO project management costs of USD 50,000 allocated in The Project Document (PD). Although the difference between the estimate at project preparation and the actual cost is less than 10%, the impact turned out significant due to the reduced budget for other activities. Some of the activities of information/sensitization (Component 1), and technical assistance envisioned in Components 3 and 4 have not been performed. Part of activities under Component 1 were implemented by another project, and not accompanied by the PM of the project under evaluation.

Results based management and UNIDO performance were both **Moderately Unsatisfactory**. The approach originally agreed upon by stakeholders for the implementation was not followed. In particular, there was no steering committee and no local project co-management or monitoring - as UNIDO ITPO office[1] ended up not being mandated to follow up the project. The potential synergies with the HCFC Phase Out project were limited to a conference prior to the start of the project - this despite of the fact that HCFC Phase Out project implemented part of the activities of Component 1 (which were also on its own project document). UNIDO PM provided adequate and timely supervision and backstopping to the project implementation until 2015, but limited to Component 2 activities. According to the UNIDO PM at the time of implementation "*contrary to the PD, no activities under Components 1, 3 and 4 could be paid from the GEF grant and hence these activities had to be fully covered by co-financing. That is why UNIDO was not involved in any activities on component 3 and 4.*"

Country ownership from the side of beneficiary companies is **Moderately Satisfactory**. Leadership from national authorities was less than satisfactory. In communication with UNIDO in 2018, MNRE reports the latest update received on the projects dated 2015. MNRE thought that the project had ended then and did not seek further information. UNIDO PM did not communicate with MNRE in the course of the January 2017 mission

The sustainability of the results is rated **Likely**. The RF has ceased to provide quotas for the import of CFCs. At the time of the evaluation, the two beneficiary companies nearly exhausted their stocks of the CFC-containing Salbutamol MDIs. Both companies have already produced and sold in the market the new Salbutamol MDI formulation. Altayvitaminy referred that normal commercial production of the new MDI would start in June 2018, while Moschimpharmpreparaty reported that the line would be in normal production by November 2018[2]. Further sustainability will depend on the capabilities of the two beneficiary companies to produce and commercialize the ODS-free Salbutamol MDIs on a competitive market basis, at affordable prices to patients, and of the generalized acceptance[3] by patients of the new formulation.

1 ITPO Russian Federation was established in 1989. It is different from a country office. Its mandate is to promote international cooperation in the economic, technological, industrial and scientific spheres between Russian enterprises, associations and organizations and firms from developed and developing countries. UNIDO ITPO office is sometimes called to support project implementation.

2 At the time of evaluation the two lines were idle due to annual maintenance and repair of the factories.

3 Companies hav been receiving complaints from patients of sour throat when using the new Salbutamol MDIs.

Recommendations

The evaluation team recommends the following:

To UNIDO:	
R1	In future similar projects in Russia ensure further coordination at country level, in particular when there are projects and/or local UNIDO offices dealing with projects of similar scope.
R2	In future projects, when introducing new drug formulation due to environmental issues, it should be ensured a better financial planning and adequate funding for awareness activities to explain patients and medical service staff what will happen and why. This may ensure a smoother transition and acceptance of the new drug.
R3	In future projects, including new technology transfer, further efforts should be made to conciliate as much as possible needs and expectations of each beneficiary company (it can be slightly different from company to company) with the rules and procedures of UNIDO procurement, and to agree upon commitments of the companies themselves, defining penalties for non-compliance. This can limit delays and promote channeling of funds to activities that companies may have more difficulties in covering.
R4	UNIDO should enforce requirements and documented procedures to ensure full handover of project-related information in case of change of project managers (PM).

Key Lessons learned

Key Lessons emerged from this project:
• There is lack of information regarding key decisions/agreements occurring during project implementation, namely on which components should be supported by the grant, which should be implemented by co-funding, and which to drop. • ***It is important to report/document key decisions and agreements occurring during project implementation for future reference, and in particular as PM and beneficiary representatives often change.***
• The limitations of the evaluation, namely the lack of institutional memory of project in UNIDO Headquarters, showcase the *need for a good information transfer when UNIDO PM changes occur.*
• The project document highlighted synergies with the HCFC Phase out in the Russian Federation Project, namely regarding steering committee meetings, and stated UNIDO ITPO office in Moscow would monitor the project. These synergies were not explored. Even the coinciding activities (namely at component 1 of MDI project) that HCFC Phase out project implemented were not taken as part of the MDI project (ex. not reported in the Project Implementation Report, PIR, to GEF). Opportunities were lost of improved implementation, visibility, and stakeholder involvement in the MDI project. Lack of information at country level has also impacted the evaluation. • ***It is important to seek more synergies between UNIDO projects occurring simultaneously on related topics, and to benefit from the presence in the country to accompany the beneficiaries and project implementation whenever there is opportunity*****.**
• In case of technology transfer projects where majority of funding is meant for purchase of equipment, application of the rule that allows to change any of the budget lines by up to 10% may have a drastic effect of the project implementation. About 90% of the GEF grant for the evaluated project was earmarked for the purchase of the MDI filling lines, and 9.6% increase in this budget line almost completely exhausted the GEF grant. As a result, a number of other planned activities, e.g. information campaign, were not implemented. • To address this issue UNIDO may consider including a Contingency reserve when developing the project budgets (e.g. 5-7% of the project budget) to mitigate the possible increase in the equipment cost in the course of the project implementation without seriously depleting budget lines for other activities.
• When implementing projects in which other ministries are also involved it is important to MNRE to keep a good dialogue, to be able to follow up the evolution of the activity, and to establish synergies and common actions (ex. awareness raising, information).

I. Evaluation objectives, methodology and process

The GEF Monitoring and Evaluation Policy (February 2006)[4] specifies that the GEF partners, in addition to conducting various other evaluations, will also evaluate projects "at the end of the intervention (terminal evaluation)". The policy states that through monitoring and evaluation (M&E) the GEF aims to "promote accountability for the achievement of GEF objectives through the assessment of results, effectiveness, processes, and performance of the partners involved in GEF activities." It further states "GEF results will be monitored and evaluated for their contribution to global environmental benefits". Similarly, according to UNIDO's evaluation policy, project and program evaluations are part of project cycle management. Evaluations serve three main purposes: to assure accountability, to support management, and to drive learning and innovation.

The terminal evaluation (TE) of the project *Phase-out of CFC consumption in the manufacture of aerosol metered dose inhalers (MDIs) in the Russian Federation* was implemented from April to July 2018. The evaluation field mission occurred on 14-18 May. The TE covered the whole duration of the project from its starting date on March 1st, 2012 (official date, although the 2 day kick off meeting occurred in October 2011) to the completion date on March 31st, 2018. The TE was conducted in accordance with the UNIDO Evaluation Policy[5] and the UNIDO Guidelines for the Technical Cooperation Project and Project Cycle[6]. In addition, the evaluation followed the GEF Guidelines for GEF Agencies in Conducting Terminal Evaluations, the GEF Monitoring and Evaluation Policy and the GEF Minimum Fiduciary Standards for GEF Implementing and Executing Agencies.

The evaluation team was composed of one international evaluation consultant acting as the team leader and one national evaluation consultant. The tasks of each team member are specified in the job descriptions annexed to the Terms of Reference (Annex 1).

The (TE) had two purposes. One purpose is to assess project performance against the evaluation criteria: relevance, effectiveness, efficiency, sustainability and impact. Another purpose is to draw lessons and develop recommendations for UNIDO and the GEF that may help for improving the selection, enhancing the design and implementation of similar future projects and activities in Russian Federation and on a global scale upon project completion.

The TE had three specific objectives:

(i) Assess the project performance in terms of relevance, effectiveness, efficiency, sustainability and progress to impact;

(ii) Identify key learning to feed into the design and implementation of the forthcoming projects; and

(iii) Develop a series of findings, lessons and recommendations for enhancing the design of new and implementation of similar on-going projects by UNIDO and GEF elsewhere.

4 The GEF Monitoring and Evaluation Policy, Evaluation Document No. 1 (GEF Evaluation O ce, 2006) is available at http://gefeo.org/uploadedFiles/Policies_and_Guidelines-me_policy-english.pdf.
5 UNIDO. (2015). Director General's Bulletin: Evaluation Policy (UNIDO/DGB/(M).98/Rev.1)
6 UNIDO. (2006). Director-General's Administrative Instruction No. 17/Rev.1: Guidelines for the Technical Cooperation Programme and Project Cycle (DGAI.17/Rev.1, 24 August 2006)

According to the Terms of Reference, the key question of the TE is whether the project has achieved or is likely to achieve its main objective, i.e. (a) through appropriate technology transfer, phase-out the consumption of 212 ODP[7] tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation (RF); and (b) reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer, a lower GHG propellant.

The key evaluation questions were the following:

a. What are the key drivers and barriers to achieve the long-term objectives? To what extent has the project helped put in place the conditions likely to address the drivers, overcome barriers and contribute to the long-term objectives?

b. How well has the project performed? Has the project done the right things? Has the project done things right, with good value for money?

c. What have been the project's key results (outputs, outcome and impact)? To what extent have the expected results been achieved or are likely to be achieved? To what extent the achieved results will sustain after the completion of the project?

d. What lessons can be drawn from the successful and unsuccessful practices in designing, implementing and managing the project?

In line with the practice adopted by many development agencies, the UNIDO Independent Evaluation Division uses a six-point rating system, where 6 is the highest score (highly satisfactory) and 1 is the lowest (highly unsatisfactory).

Evaluation data was collected through desk and literature review of documents and stakeholder consultations. The desk and literature review covered the original project document, monitoring reports (such as progress reports, back-to-office mission reports), as well as project outputs reports, minutes of meetings, correspondence with the beneficiary companies, reports on assessments of bids for equipment supply, and other operational documents (see Annex III).

Stakeholder consultations were performed during the field mission using semi-structured interviews. Main stakeholders were the beneficiary companies Moschimpharmpreparaty (Moscow-based production facility), and Altayvitminy (Byisk-based production facility), as well as the Ministry of Natural Resources and Environment (MNRE) that overviewed the activities, and facilitated processes such as tax exemption of imported equipment. During the field mission the evaluation team visited the plants in which the production lines have been installed.

Evaluation findings, conclusions and recommendations were discussed in detail at physical face-to-face de-briefing to the key stakeholders. Moreover, a debriefing has been held in Vienna UNIDO-HQ, joining among others, the current PM, the IED coordinator, the head of Montreal Protocol Division, the GEF representative and some other UNIDO staff. The purpose of the de-briefing was a

[7]Ozone Depletion Potential, UNEP (2006). R11=1

factual verification of key findings and an in-depth discussion of evaluation results. The feedback and comments received at the de-briefing have been considered in this report.

The evaluation has several limitations. Part of the limitations were related with the large delay (4 years) in the project implementation, due initially to lack of final agreement between beneficiary companies and equipment supplier, and requests for changes in equipment specifications, and later to Moschimpharmpreparaty not being prepared to receive/set up the equipment. Other limitations that restricted the amount of information available for the evaluation team include:

- In 2018 many people who were involved in the original formulation and early implementation (the project was launched in 2012) of the project were not available for interview with the evaluation team. For example, Chief Engineer of Moschimpharmpreparaty who reportedly was the main driving force behind the project implementation in that facility retired couple years ago, and his successor met with him only once and did not get much information about the project;
- The project was managed from the UNIDO office in Vienna, and contrary to what had been foreseen in the project document[8] UNIDO's ITPO Moscow office was not involved in the project. As a result, there was no institutional memory about the project in that Moscow office;
- The change in the project management at the UNIDO office in Vienna – the two project managers that implemented nearly all of the project activities are no longer at UNIDO - combined with the considerable delays in the project implementation lead to the loss of organizational memory about the project at the headquarters level. As a result the evaluation team has received a limited package of the project documentation and no stakeholder contacts in Russia from the Vienna office. Stakeholder contacts were eventually obtained from Mr. Christian Wolff who is the director of the technology supplier company, that supplied equipment to Russian facilities;
- As the project management did not have direct contacts with the Ministry of Health and Roszdravnadzor, at least recently, these organizations did not maintain any organizational memory about their involvement with the project and their representatives were not available to meet with the evaluation team;
- The project evaluation field visits coincided with the maintenance and repair period of the facilities when the production was stopped, so the evaluation team was not able to observe the new MDI lines in operation.

[8] According to the project document: "The UNIDO office in Moscow will be a coordinator of the whole GEF programme in the RF including the monitoring this project implementation"

II. Country and project background

2.1. Brief country context and project background

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 chlorofluorocarbons-11 (CFC-11) and CFC-12) was fully phased out on December 20, 2000.

However, the CFC phase-out program 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 were being produced by the two Russian enterprises, i.e. Altayvitaminy, Biysk, Altay region and Federal State Enterprise Moschimpharmpreparaty , Moscow and to meet asthma patient demand, and the Russian Federation had to require CFCs for the production of Metered-dose Inhalers (MDIs).

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 should be achieved by 2008. However, by 2010, those two MDI producers were still consuming annually about 212 MT of CFC-11 (solvent) and CFC-12 (propellant) needed for production of the asthma rescue medicine Salbutamol MDI. Funds and technical assistance were required by the two companies to be able to convert the production lines from CFC containing MDIs to ozone-friendly hydrofluorocarbons HFC-134a MDIs.

Decision XXI/4(8) of the Meeting of the Parties (MOP) requested the Technology and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC) to “organize and undertake a mission of experts to examine the technical, economic and administrative issues affecting the transition from using CFC to CFC-free alternatives in the production of Salbutamol MDI in the Russian Federation, and to report the results of this mission to the meeting of the thirtieth Open-ended Working Group.

The TEAP concluded that financial support was the main priority and recommended that *GEF funding should be investigated urgently as the first option since finance governs the success of the transition in the Russian Federation*. Based on the TEAP/MTOC mission, the Parties could have expected that 18-24 months would be the overall time for conversion of the two enterprises once funding was approved by the implementing agency.

To achieve that goal, the two MDI producing companies required technology transfer from one, or more, established multinational enterprises with experience in the development and manufacture of MDIs using CFC-free technologies, and with 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.

The project under evaluation was designed to address the above-mentioned RF priority of phasing-out CFCs in the Russian Federation by the end of 2012. The GEF was the main donor of the project. Co-funding for this project was leveraged from the two pharmaceutical companies benefiting from the project: Moschimpharmpreparaty, Moscow and Altayvitaminy, Biysk, Altay region. UNIDO also contributed in cash and in-kind.

2.2. Project Summary

The project *Phase-out of CFC consumption in the manufacture of aerosol metered dose inhalers (MDIs) in the Russian Federation* has two main objectives: (a) through appropriate technology transfer, to phase-out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation; and (b) to reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer, a lower GHG propellant.

The expected outcomes of the project were:

i) Policies reviewed and CFC legislation improved, if necessary; ODS and CFC import/export legislation updated to reflect final phase out of CFCs in MDIs;

ii) To meet Montreal Protocol, phase out obligations (Phase out of 212 ODP tones of CFC - CFC-11 and CFC12); and Technical assessment of production capacity within the MDI sector;

iii) new MDI products that meet national and international standards designed and developed; iv) New MDI products registered at the Ministry of Health for use.

The referred outcomes would be achieved through the production of 17 outputs. The project results framework is included as Annex 1 of the ToR of this assignment, and will be discussed below.

Table 1 provides all relevant information regarding project costs and co-financing, donors, duration, implementing and executing agencies.

Table 1 Fact Sheet of the project

Project title		
UNIDO PROJECT ID	100352	
GEF Project ID	4387	
Actual start date	1/3/2012	
Planned end date Revised end date	30/04/2014 31/03/2018	
Project Costs (in USD)	GEF grant:	2,550,000USD
	Co-funding UNIDO: Private Sector	 100,000USD 5,500,000USD
	Total	8,150,000 USD
Implementing agency: Executing partners:	UNIDO Mostly the beneficiary companies and the technology provider.	
Mid - term review date	A mid-term evaluation/review was not conducted.	

2.3. Project implementation arrangements and implementation modalities

UNIDO was the GEF project implementing agency. UNIDO-HQ implemented the project directly, dealing with the two beneficiary companies and the equipment supplier directly. A national consultant was hired from March to June 2012, to facilitate the preparation of implementation of Component 2 of the project, namely procurement of the equipment. Communication was maintained between UNIDO-HQ and the Ministry of Natural Resources and Environment regarding the implementation of the project, particularly until 2015.

According to the former UNIDO-HQ PM, Mr Dalibor Kysela, the two purchase orders to Pamasol, company selected as supplier of the CFC-free MDI filling line, were signed in November 2013 in a total amount USD 2,521,395. This exceeded the USD 2,300,000 allocated for equipment procurement (Component 2 of the project) according to the approved Project Document. Therefore, the two factories implemented directly all the necessary activities to design and develop the new MDI products and to have them registered (Components 3 and 4) and were able to place the product in the market. According to Mr. Kysela UNIDO was not involved in any activities on formulation and registration of new product (components 3 and 4).

UNIDO ITPO Office in RF provided specific support to the project when requested. For example, UNIDO ITPO Office provided support when UNIDO-HQ PM travelled to RF and also supported the process undertaken by Altayvitaminy of requesting customs tax exemption for the MDI production lines equipment. The team of the project *Phase Out HCFCs and Promotion of HFC-Free Energy Efficiency Refrigeration and Air-conditioning Systems in the Russian Federation through Technology Transfer* (UNIDO ID: 105324; GEF ID: 3541) (hereinafter referred and HCFC-phase out project) implemented some activities foreseen under Component 1 of the MDI project at the expense of their project, including

trainings/support to customs officers on CFC phase out, and organization and conveyance of an international expert group meeting to discuss ODS free MDIs (2 days in October 2011). However, the activities implemented by the *Phase Out HCFCs* project are not described in the MDI (GEF ID 4387) Project Implementation Reports to GEF.

Table 2 presents the list of institutions that have been involved in the project implementation:

Table 2 Stakeholder map

Stakeholder	Involvement
Ministry of Natural Resources and Environment	Responsible for the total CFC phase out in the RF and it has been involved in execution of the ODS Phase-out Program of the RF
Ministry of Health and Population	Responsible for monitoring the use of CFC-based MDI production and use in the RF, and for all necessary arrangements associated with control and monitoring of CFC-free MDI imports into the country
Roszdravnadzor	Registration of new formulations
Altayvitaminy	Byisk-based production facility - beneficiary company with a production line of HFC-134a propellant MDI
Moschimpharmpreparaty	Moscow-based production facility - beneficiary company with a production line of HFC-134a propellant MDI
PMU of HCFC Phase out Project	The following activities that have been included in the project results framework of this project, have been carried out and budgeted on the HCFC Phase out program: i) Training to 50 customs officers done and procurement of ODS control equipment for customs; ii) within the Awareness, educational information and environmental management systems upgraded output a Regional Expert Group Meeting on (EGM) on development of national strategies for elimination of CFCs contained in aerosol metered dose inhalers (MDI) in the Commonwealth of Independent States (CIS). The later event occurred prior to the official starting date of the project.

2.4. Theory of Change

The evaluation used Theory of Change (ToC) approach to assess the project's contributions to the conditions leading to the desired behavioral and technological transformations. As the project document does not contain a Theory of Change, the evaluation team has re-constructed the project Theory of Change (ToC) on the basis of the information in the Project Document and data from the interview with representatives of the Russian Ministry of Natural Resources and Environment who were involved in the project design.

The ToC, in Figure 1, presents the project results map, that is the sequences of intended project results leading to the project objectives, as well as assumptions related to achievement of each of the project results. For example, if the result "CFC legislation, including export/import regulations improved" is achieved, then the next result "Import of CFC-11 and CFC-12 stopped" can be achieved if the improved legislation is effectively enforced. The ToC also shows a second objective of project reported to the evaluation team by the MNRE representatives, which is to ensure availability of salbutamol MDIs for Russian asthma patients, as the two facilities supported by the project were the main manufacturers of this medication in RF.

While the Project Document identifies four project components, the evaluation team has identified three interrelated chains of results. The top sequence of results presents how the Project was seeking to establish a legal framework that would prevent the MDI manufacturers to use CFC-11 and CFC12, and lead to the phase-out of their use. The central chain of results shows how the transfer of technology was expected to lead to continued access of Russian asthma patients to vital salbutamol medication. The third sequence of results - development and registration of new salbutamol formulation for new ozone-safe MDIs - feeds into the central chain of results. The top chain of results also feeds into the central one, because it was expected that the manufacturers would stop the old production lines using CFC-11 and 12 before starting the new production lines purchased with the support of the project.

Given that GEF funding covered about one third of the estimated project costs and the rest was to be covered by the MDI manufacturers, many of the assumptions associated with achievement of the intended results have to do with the manufacturers' ability to provide the necessary co-funding and make all necessary arrangements to prepare for the launch of the production of ozone-safe MDIs. Another important assumption is that the RF government would be able to effectively enforce legislation banning imports of CFC-11 and 12, which is crucial to stop the production of the ozone-unsafe salbutamol MDIs.

Figure 1: Theory of Change

CFC legislation, including export/import regulations improved	➔	Import of CFC-11 and CFC-12 stopped	➔	Production of CFC-11 and CFC-12 based salbutamol MDIs stopped	➔	212 ODP tones of CFC-11 and CFC-12 are phased out
Assumptions: • Legislation cannot be improved without project support		Assumptions: • Legislation is effectively enforced • Customs agents are trained and equipped		Assumptions: • MDI manufacturers don't have access to CFC-11 and CFC-12		
				↓		
Equipment for production of ozone-safe salbutamol MDIs is provided to two enterprises	➔	Equipment for production of ozone-safe salbutamol MDIs is put into operation	➔	Production of ozone-safe salbutamol MDIs started	➔	Russian asthma patients have access to salbutamol MDIs
Assumptions: • Manufacturers are able to provide necessary co-funding • Manufacturers are able to manage custom formalities		Assumptions: • Manufacturers are able to prepare and execute the launch (e.g. cover the cost of FAT, preparation of premises, provide necessary additional equipment) • Manufacturers are able to perform pilot and experimental batches		↑ ↑ ↑ ↑ ↑		Assumptions: • Production of new formulation is economically viable • Cost of the new formulation is comparable with the old one • New formulation is as effective as the old one • Patients accept the new formulation
New salbutamol formulation for ozone-safe MDIs is developed	➔	New salbutamol formulation for ozone-safe MDIs is registered by the Ministry of Health	➔	↑		
Assumptions: • Manufacturers are able to cover related costs • Manufacturers have access to necessary expertise		Assumptions: • Manufacturers are able to cover related costs • New formulation successfully passes the tests				

It is important to note that, according to the Project Document, the level of investment associated with the three chains of results varies considerably. The majority of the project expected funds (92% of GEF grant, and with co-financing 7 out of 8.15 million USD) were associated with achievement of the central chain of results, and only 0.85 million USD were associated with the achievement of the bottom chain of results.

The evaluation team used the reconstructed ToC to analyze if all result sequences unfolded as expected and eventually lead to achievement of the project objectives. The level of detail in Figure 1 was selected to ensure readability of results map.

2.5. Major changes to project implementation

As stated above, the two purchase orders to equipment supplier Pamasol exceeded the USD 2,300,000 allocated for Component 2. UNIDO had no funds left for Component 3 (formulation of new product) and Component 4 (registration of new product). Component 1 was also not fully implemented. Part of Component 1 was implemented by the HCFC Phase-out project, because there was some overlap in terms of planned activities between the two projects, but this has not been reported in the Project Implementation Reports (PIR) of the project under evaluation.

The project was consecutively managed by 4 UNIDO-HQ project managers. The PM who initiated the project implementation was replaced in March 2013 when he left UNIDO; the second PM was in post until 2017 when he left UNIDO; the PM who initiated the project TE process started in 2018 for a few months, and was replaced after the field mission by another PM. The most recent PM is the expert who designed the project.

As can be seen in section 2.3, the level involvement of UNIDO ITPO Office in Moscow and of PMU of the HCFC Phase-out project were lower than foreseen in the Project Document[9]. Moreover, no Project Steering Committee meetings have been organized

2.6. Positioning of UNIDO Project

UNIDO is one of the Montreal Protocol (MP) Implementation Agencies responsible for development of MP programs and projects worldwide. The MDI project in the RF fits into the UNIDO program to achieve the total phase out of CFCs and HCFCs by making conversion to other technologies and designing energy efficient products.

[9] According to the project document: “In order to use efficiently funds, it is suggested that this UNIDO CFC Phase out Project in the MDI sector can be also monitored by the Project Monitoring Unit (PMU) established for the HCFC Phase out Project in the Russian Federation, especially in organizing annual PSC meetings. The UNIDO office in Moscow will be a coordinator of the whole GEF program in the RF including the monitoring this project implementation”
”

As seen above, the project follows the recommendation of the TEAP/MTOC of MP to seek financing at GEF Ozone Focal Area for Countries with Economies in Transition (CEIT) to address the urgent need to RF to completely phase out CFC consumption. Besides, technical assistance to the companies producing MDI was required for conversion. The Government of the RF has requested UNIDO in 2009 to provide technical assistance to the two enterprises with converting CFC-based production of the MDIs into CFC-free one.

UNIDO has been involved in the MDI conversion process worldwide 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. By the time of endorsement of this project, the projects in Iran and Mexico had been successfully completed.

III. Project Assessment

3.1 Progress to Impact

The project intended to address a specific problem of the two companies that required funding and technical assistance to produce a new formulation of ODS-free salbutamol MDI, and stop the consumption of CFC in RF. The project design also contained an institutional development component and a users and health staff awareness raising and sensitization campaign to promote the new MDI formulation (Component 1). Although the government and the HCFC phase out project did implement some institutional development activities, the project implementation reports do not mention specific activities performed under component 1.

At the time of evaluation, the two beneficiary companies were not yet producing the new MDI on a regular basis, although all tests had been performed and some new salbutamol MDIs had been already sold in the market.

Regarding the aspects that measure progress to impact, scaling up does not apply, and mainstreaming could derive mostly from the institutional and awareness raising activities of Component 1, part of which have not been implemented by this project or have not been implemented at all. This project was built on UNIDO experience of implementing several projects similar to this one across the globe. Reportedly this was one of the last MDI conversion from CFC projects implemented globally, so aspects of replication of the project elsewhere are not too relevant

Regarding UNIDO's dimensions of progress to impact: In 2015 RF government ceased allocating quotas to Altayvitaminy and Moschimpharmpreparaty for the import and use of CFC-11 (solvent) and CFC-12 (propellant) for production of asthma rescue medicine Salbutamol MDI. New ODS-free Salbutamol MDI production lines are in place and are expected to be in full operation by the end of 2018, and patients are expected to continue to have access to the medicine[10]. Regarding Component 1, the companies referred that one of the major weaknesses of the project was the lack of information to patients and medical staff about the reasons to change formulation and the effects on patients. The companies have received quite some complaints[11] from the patients when the ODS-containing Salbutamol MDIs started to be replaced by the new formulation. It is not possible to analyze economic performance at this stage, as the companies are still not producing the new Salbutamol MDIs on a regular basis.

By the time of the evaluation, it was still possible to buy the old (90 dozes) CFC-based salbutamol MDIs, although already in limited places. For example, in a popular online network of pharmacies, Altayvitaminy old CFC-based Salbutamol MDI was only available in one store, while the old 90 dozes CFC-based MDI produced by Moschimpharmpreparaty could be found in 43 stores.

[10] It came to the evaluators' knowledge that another RF Joint Stock company is producing and commercializing ODS-free Salbutamol since 2011.
[11] Reportedly the most common complaint is that the new formulation promotes throat pain.

It can be stated that the project has provided an important financial support for the establishment of the production lines and supported procurement, which was a breakthrough. The project provided a very relevant contribution to definitively phase out consumption of CFC in RF. But not all results were yet achieved (mass production has not started). This will be further explained in the next sections.

The rating on progress to impact is **Moderately Satisfactory**.

3.2 Design

As seen in Section 2.1, the project was designed specifically to address the urgent need of RF to phase out CFC use in the production of MDIs. RF has requested UNIDO to implement the project based on previous experience. Reportedly, the grant amount reflects GEF reply to the request of funds made by the Parties to the Montreal Protocol, and the project has been designed knowing the available amount. Moreover, there are only a few companies in the world that can provide the quite specific ODS-free Salbutamol MDI production equipment. Under these circumstances it is difficult to estimate price of the equipment, as there might be specificities that were not initially foreseen. This besides price fluctuations that may occur, as a couple of years go by between project formulation and actual procurement.

The project design has also taken into consideration the existence of the project (UNIDO ID: 105324; GEF ID: 3514) *Phase Out HCFCs and Promotion of HFC-Free Energy Efficiency Refrigeration and Air-conditioning Systems in the Russian Federation through Technology Transfer*, and tried to establish synergies. In fact, part of the activities considered in Component 1 were a continuation/complement to activities of the HCFC-Phase out project, or even to be implemented by it. Similarly, regarding monitoring and evaluation (M&E), the project document establishes a link with the HCFC-Phase Out project, using the PMU, and UNIDO's ITPO Office to carry out the M&E activities, and the Steering Committee meetings.

Within the context referred above, the project document contains an appropriate stakeholder analysis. The project document also describes clearly the implementation arrangements and the roles of key partners. However, as the project has been implemented by several consecutive UNIDO-HQ PMs, the project implementation arrangements and implementation modalities ended up being different from what was planned.

The Project Document informs about the evolution of CFC phase out in RF, as well as why CFC was still being used in MDI production, and frames it within the international context. The Project Document identified the main barriers that needed to be addressed to promote conversion from CFC-based to HFA-based Salbutamol MDI.

The overall objective of the project reflects its main purpose. The objectives are *(a) through appropriate technology transfer, to phase-out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered- Dose Inhalers (MDIs) in the Russian Federation (RF) and (b) to reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer a lower GHG propellant.*

In fact, in some circumstances a Salbutamol MDI may be a life saving medicine, and Salbutamol MDIs are part of the list of life-saving drugs of the MoH of RF. This justifies the quotas of CFCs for Essential Use Nomination that RF requested to Montreal Protocol for the MDI production. Requests were 2009 (241 MT), 2010 (212 MT) and 2011 (248 MT), and 212MT for each 2012, 2013 and 2014. However, the Meetings of the Parties to the Montreal Protocol were pressuring RF to cease producing CFC-containing MDIs. Besides as CFC production becomes scarcer, its price in the international market is prone to increase. With the project, the two plants will start producing Salbutamol MDI using HFC-134a propellant; HFC-134a has a Global Warming Potential[12] over 100 years of 1300, which is lower than CFC 11 (4660) and CFC 12 (10200).

Other purpose of the project, which is continuity of availability in the market of Salbutamol MDI at affordable price for Russian asthma patients, requires timely implementation of Components 3 and 4 of the project, which are formulation and registration of the new medicine. These are not reflected in the objectives. Component 1 was designed as institutional capacity development to support the transition.

Project potential risks have been identified and described and some adequate mitigation measures have been proposed. The core of the project design was based on UNIDO's experience of conversion of 16 MDI products in the world with an HFC-134a propellant, applying a new formulation and a new design of the MDI product. An alternative solution had been foreseen in case the selected supplier of technology would not comply with the task on new MDI development and formulation. However, the risk of *delays in project implementation and coordination of project activities* ended up being higher than foreseen in the project document (and affecting the project implementation) and there were no mitigation measures. In the case of Moskhimpharmpreparaty, the PIR 2016 states that the "Factory building is old (1887) and belongs to the cultural heritage of city of Moscow. That's why it requires complete refurbishment including control of static. The risk is completely out of control of the project team, therefore, no mitigation measures available".

The distribution of the budget revealed some problems, part of which due to the circumstances referred at the end of Chapter 3.1. The technology transfer (component 2) ended up costlier than budgeted and deprived other components of their funds. The project design allocated to component 1 *Institutional and regulatory capacity building for ODS phase-out* a very limited amount of USD50,000. The project foresaw a co-financing by the beneficiary companies of USD100,000, and part of the activities were assumed to be addressed through the Ministry of Health but no quantification of co-financing was estimated. This was a risk and proved to be so. Some of the activities were implemented by other entities and projects, but judging from the PIRs, the project management disengaged from this component. Relevant activities (information/sensitization) were not implemented. The high level of co-financing of Components 3 and 4 is adequate, as companies need to implement those components in order to be able to commercialize the new MDI. The amount of grant allocated to those components - USD100,000 for component 3 and USD50,000 for component 4 -

[12] https://www.ipcc.ch/pdf/assessment-report/ar5/wg1/WG1AR5_Chapter08_FINAL.pdf

would have been used to provide technical support. The project did not provide this technical assistance.

The proposed monitoring and evaluation (M&E) plan was very generic, focusing on preparation of reports but not detailing or budgeting how to implement M&E. The plan turned out to be unrealistic. It mentions that the yearly report should inform the Project Steering Committee meetings, but there was no PSC. The annual review meetings of the project did not always take place. The M&E plan also mentions a mid-term review, but it has never been done.

A Project Results Framework (PRF) (Annex A of the Project Document) includes the expected outputs of the project and the proposed indicators and sources of verification for the project. Most of the proposed indicators are SMART and can be easily verified. The outcomes and objectives are included in the project framework. The outcomes of Component 1 and outcome 2.2 are not adjusted to the outputs. There are no outcome and objectives indicators.

The PRF contains a list of assumptions and risks - at output and activities level - which seem realistic and would allow achieving success. However, the risk that as designed the project management would end up focusing only on the preparation of the production lines and formulation/registration was not considered.

The rating on project design is **Moderately satisfactory** and the rating of Logframe is **Moderately unsatisfactory**.

3.3. Relevance

This project is highly relevant. As described in Section 2, the project supports the RF compliance with the Montreal Protocol obligation of phasing out production and consumption of CFC, while providing the required technical assistance to convert the production of CFC metered-dose inhalers (MDIs) to ozone-friendly HFC -134a at the two national companies producing Salbutamol MDI, a lifesaving drug.

In 2011 (on June 22, 2011) Presidium of the Russian Government reviewed the state system for control of the ODS13. Starting from 2010 Russia had to reduce the consumption of the ODS threefold to comply with the Montreal Protocol, so additional measures were necessary. One of the decisions issued by the Presidium of the Russian Government was to develop and implement activities necessary to stop consumption of the ODS in the MDI production. The Industry and Trade Ministry and the Natural Resources Ministry in cooperation with other state institutions were tasked with the development of the set of measures to stop production of ODS-containing goods by 2015.

The Presidium of the RF Government decisions also included the development of changes in custom regulation on the ODS and training for custom officers. Although the referred activities are included in this project, the very same were also included within the HCFC-phase out project, and were implemented by that project.

[13] http://www.unido-russia.ru/archive/num4/art4_6/

Relevance to GEF

The 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 212 MT of CFCs. It is an annual amount of CFC to be phased out at the two Russian MDI producers (see Chapter 3.2 para. 5).

GEF has been approached to provide the grant following a recommendation of the Technology and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC) of Montreal Protocol, based on a mission of experts undertaken to examine the technical, economic and administrative issues affecting the transition from CFC MDI to CFC-free alternatives in the Russian Federation. The mission had been requested by the Decision XXI/4(8) of the Meeting of the Parties (MOP) of Montreal Protocol.

UNIDO’s Comparative Advantages

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 Salbutamol MDIs into CFC-free ones.

UNIDO has been involved in the MDI conversion process worldwide 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. By the time of endorsement of this project, the projects in Iran and Mexico had been successfully completed.

In parallel to this project, UNIDO was implementing the USD40M HCFC Phase out Project in the Russian Federation. The project document established synergies between the two projects.

The rating on relevance is **Highly Satisfactory**.

3.4. Effectiveness

As stated in the Project Document, 18 outputs, organized under four components were expected to be delivered that would contribute to 6 outcomes (see next table). The following paragraphs discuss the achievement of outputs and outcomes during implementation. As stated above some outcomes do not seem to match the outputs.

Outcome	Output	Interventions
Component 1: Institutional and regulatory capacity building for ODS phase out		
1.1. Policies reviewed and CFC legislation improved, if necessary. 1.2. ODS and CFC	1.1 Analysis of the level of the residual demand of CFC after 2010 by looking at the stock of ODS in the country made	Request from the Government for EUN quota for the RF without looking at the stock of ODS in the country. Policies reviewed and CFC legislation checked.

import/export legislation updated to reflect final phase out of CFCs in MDIs.		CFCs consumption and import analyzed.
	1.2. Training of 50 customs officers done and procurement of ODS control equipment for customs made	Check with the customs, whether CFCs control equipment is available. Conduct training for custom officers on difference between HCFCs and CFCs.
	1.3. Two MDI producers and CFC supplier framework developed and commitments made	Further collection of MDI production and import data in the RF. Along with the two CFC-based MDI producers, at least one additional HFA-based MDI company is known.
	1.4. Awareness, educational information and environmental management systems upgraded	Brief local public relations officers at the Ministries on the ban of CFC use in the RF Develop a plan for 2 years for communications purposes: preparation of leaflets, placates on the project which deals with complete CFC phase out in the country
	1.5 At least two centralized training symposia to train representatives from the Ministry of Health conducted	To develop a training course for doctors, pharmacists, lung specialists on the new HFA MDIs techniques including the details of new therapy
	1.6. Policies reviewed, relevant laws and regulations in place	Domestic legislation is necessary to accommodate CFCs free MDIs
Component 2: Phase out of CFC consumption in the Medical Aerosol (MDI) Sector		
2.1. To meet Montreal Protocol phase out obligations (Phase out of 212 ODP tones of CFC (CFC-11 and CFC- 12)) 2.2. Technical assessment of production capacity within the MDI sector	2.1. Aerosol filling line/s with two dispensers in a double stage filing process at Moschimpharmpreparaty and line/s with two indexing machines in a single stage filling process at Altayvitaminy installed	Alternative technologies are to be selected for the two MDI producers TORs for equipment procurement are prepared by UNIDO
	2.2. Guidance of the Russian experts on the MVP - Installation Qualification (IQ), Operational Qualification	Preparation of the Master Validity Plan, including GMP certification to conduct IQ, OQ and PQ tests

	(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 made	All engineering aspects of MDI production need to be verified and validated Engineering Plan need to be prepared
	2.4. Assistance (new MDI-Salbutamol production, engineering services, equipment and instrumentation, etc.) for conduction of three pilot batches rendered by a technology provider	Engineering plan developed for production of three pilot batches of new MDIs by a technology provider Provision of all necessary materials on part of technology provider
	2.5. Three experimental batches of a new MDI (1500 pcs) together with a reference placebo batch (minimum placebo 500 MDIs) carried out at the two enterprises	Engineering plan developed for production of three experimental batches of a new MDI (1500 pcs) together with a reference placebo batch (minimum placebo 500 MDIs) Provision of all necessary materials on part of project counterparts
	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	Engineering Plan developed for pilot production of a final batch of new MDI. Provision of all necessary materials on part of project counterparts
Component 3: Technology Transfer for developing a new HFA-based MDI		
3.1 Design and development of new MDI products that meet national and internationals standards	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	Drafting TOR for a technology provider, Job Description for an international consultant Preparation of tendering documents
	3.2. All materials and primary packaging components (valve, canister and actuator), of the MDI product excluding	Inclusion of all materials and packaging components in the TOR for technology provision

	the secondary packaging components (carton, package insert etc.) selected	
	3.3. Final conversion of CFC based MDI Salbutamol 200 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	Conduction of 6 months stability tests proving that the new MDI Salbutamol 200 dose, 100 µg/ dose label claim meet the technical requirements of the Drug Regulations of the Ministry of Health
Component 4: New developed MDI products registered at the Ministry of Health		
4.1 New MDI products registered at the Ministry of Health for use	4.1. 2 or 3 key events [pilot production, stability tests of new MDI] in the Working Plans of the companies included	Pilot production, stability tests of new MDI in the Working Plans of the two enterprises included
	4.2. 2 or 3 key events [testing results from the local labs, MDI registration] in the Working Plans Rossdravnadzor included	Testing results from the local labs submitted, MDI registration timing in the Working Plans of the Rosssdravnadzor included
	4.3. Clinical test and final registration of new MDI products achieved	A meeting and follow up with Rossdravnadzor on registration procedures of new MDIs conducted.

It should be highlighted that the two purchase orders to the supplier of the new Salbutamol producing technology were signed in November 2013 in a total amount USD 2,521,395. This corresponds to about 99% of the total GEF grant. The former UNIDO PM who was in duty at the time of implementation reported that as most of the grant funding was exhausted to purchase equipment, UNIDO ended up not being involved in any activities on components 3 and 4.

Component 1 aimed on one hand at phasing out the import of CFC, via improved legislation, and law enforcement by training customs agents - as described in the theory of change (section 2.4); and, on the other hand to sensitize relevant authorities, health staff and the general public on the new HFA formulations required to replace CFC-containing Salbutamol MDIs, to ensure a smooth transition and contribute to acceptance of the new project. Component 1 can be seen as having several subcomponents: i) gather information on CFC imports and consumption in the country, and on other companies using HFA-based MDIs, in order to contribute to the improvement of the policy and legislation to phase out import of CFC completely - according to project document this actual improvement (activity 1.6.) should be implemented by the Ministry of Health; ii) communication to ministries public relations officers, and preparation of a 2 year communication on the ban of CFC use in the RF, and the consequent need for HFA-based Salbutamol MDIs and promotion of the product; iii) a training course

for custom officers on difference between HCFCs and CFCs; a training course for doctors, pharmacists, lung specialists on the new HFA-based Salbutamol MDI techniques including the details of new therapy.

The project implementation reports (PIR) to GEF only report on Output 1.1. The PIRs also report that CFC import has been phased out by the legislation. No application for exemption was submitted by RF any longer after 2015. The activities leading to the output *Training of 50 customs officers done and procurement of ODS control equipment for customs made* have been implemented by the HCFC Phase out project. Also, prior to the commencement of the project a 2 days workshop was organized and delivered by the HCFC Phase out project. This workshop focused on MDI and participating companies could present their technology for ODS-free MDI production - this can be seen as an information/sensitization activity. No other activities have been conducted.

In conclusion, the institutional component of the ToC (first line) has been completed, but the project under evaluation has not directly implemented activities leading to it. Besides, the beneficiary companies point as a negative aspect of the project the lack of awareness raising, and information for the patients regarding the need for the change in formulation and the differences of the new formulation. The companies received quite some protests from patients as the new formulation uses ethanol and impacts on the throat. The 2-year communication plan, and the training course for doctors, pharmacists, lung specialists have not been performed.

Component 2 - The project (UNIDO) has provided support in the preparation of the ToR for equipment, international bidding, and selection of equipment supplier for both companies. The project has also supported the issuing of Purchase Orders for equipment for both companies, and the organization of technical meetings with the beneficiaries at the premises of the supplier (Moskhimpharmpreparaty in April 2014 and Altayvitaminy in June 2014) to discuss layout and technical details of the ordered equipment.

The working arrangement between UNIDO and the beneficiary companies establishes that the companies shall provide: i) all civil engineering and construction work required for the overall implementation of all the conversion process; and ii) all required mechanical, piping, electrical, instrumentation, testing and any other work, labor, services, supplies, utilities and supporting systems, for the erection, commissioning and start-up of the new manufacturing equipment and for the trials, test runs and full scale safe production. In both cases the scope of work indicates that it ought to be further specified with the assistance of the suppliers in line with their contractual obligations.

According to the technology supplier (PAMASOL), its role was limited to the supply of the filling lines. This means that the beneficiary did implement the necessary activities for the experimental batches without the foreseen technical assistance provided by the project - namely on developing the engineering plans for production of pilot and experimental batches of a new MDI. The PIRs do not contain information on implementation of component 2 activities, except for purchasing/delivering production lines.

UNIDO Moscow ITPO office supported Altayvitaminy with getting tax exemption

for the production lines. Moskhimpharmpreparaty missed the timely application to customs to obtain import clearance permission under special conditions, and did not get tax exemption.

As stated above UNIDO has not been involved in Component 3 and Component 4. Both companies have already commercialized the new ODS-free Salbutamol MDIs, even if they are still not producing it on regular commercial basis. The beneficiary companies, autonomously from the project, did the necessary investments and arrangements, and actions to be able to commercialize the product. Altayvitaminy reported in 2016 that it invested 23.95 Million RUB for services and works related to installation of the new MDI production line, and for testing and registering the new MDI-Salbutamol. This is the only existing data regarding co-financing.

In summary, RF is no longer requiring quotas for CFC imports since 2015. At the time of the evaluation (May 2018) the beneficiary companies have already produced and commercialized the new HFA Salbutamol MDIs, although not yet on a regular commercial basis. Looking at the ToC, the results of the project have been achieved up to the point in which the production of new Salbutamol MDIs starts on a regular basis. Asthma patients so far continued to have access to the old CFC-based Salbutamol MDIs as the stocks continued to be sold. The GEF grant, and UNIDO support have been crucial for the purchase/installation of the equipment, but all the remaining aspects of the project - without which the investment would have been irrelevant - are due to the beneficiary companies. RF authorities and HCFC-Phase out project implemented part of Component 1 activities. Part of project activities has not been performed. Thus it can be concluded that external factors (the other project, the need of companies to recover investment and their interest to continue in the market) contributed highly to the achievement of the results. The project itself unlocked the situation - this aspect is valuated on progress to impact.

For the reasons presented above effectiveness is rated Moderately **Satisfactory**.

3.5. Efficiency

The project started in January 2012, and was initially planned to end in December 2014 (24-month duration). By 2016 Altaivitaminy had started producing the new product Salbutamol 200 and Salbutamol 300 for the Russian Federation and was obtaining registration of the product in other countries (Armenia 2016, and Kyrgyzstan 2017). The implementation at Moskhimpharmpreparaty was further delayed, the company got ready to receive the new production line only in 2017. The new production line was installed in June 2017, and in October 2017 the Site Acceptance Test (SAT) was executed, the work has been completed successfully and the SAT protocol was signed (the line was commissioned). At the time of evaluation, none of the plants was yet producing the new Salbutamol on a regular basis. Altayvitaminy referred that normal commercial production of the new MDI would start in June 2018, while Moschimpharmpreparaty reported that the line would be in normal production in November 2018.

Implementation progress was first affected by the fact that beneficiary companies did not reach a full agreement with equipment supplier in the international bidding

and wanted to change some specifications. In consequence the project was extended by 1.5 years. For Altayvitaminy the shipment has been accepted in November 2015. Moschimpharmpreparaty missed to apply for the import customs clearance permission under special conditions, and has asked the supplier to store the equipment. Once the equipment has been delivered to Moschimpharmpreparaty, the company informed the supplier that infrastructure was not ready due to lack of funds, and as the company had had no general director it was not able to act. Only in June 2017 the supplier was authorized to execute the installation.

It has been explained above that the original budget was insufficient for UNIDO to provide all the expected support. The project grant was limited to Component 2, which has affected project results - namely Component 1. The expected co-financing materialized, and the beneficiary companies themselves have administered it. Altayvitaminy provided a list of activities undertaken in 2016 with the corresponding costs. However, there is no other information on the amounts of co-financing invested by the companies or by the RF authorities.

Arguably if the implementation of the project had followed more closely the project document, making use of the synergies referred, more would have been achieved with the same input.

For the reasons expressed above efficiency is rated **Moderately Unsatisfactory**.

3.6. Sustainability of benefits

Regarding financial risks, the sustainability of project benefits is moderately likely. The beneficiary companies have already demonstrated the commitment to the project, as they have done the necessary investments to produce the new MDI. The financial sustainability of the results will depend on the capabilities of the two beneficiary companies to produce and commercialize the ODS-free Salbutamol MDIs on a competitive market basis, at affordable prices to patients, and on the capacity of the companies to improve the formulation so that patients will stop feeling sour through when using the Salbutamol MDIs.

Regarding socio-political risks, the sustainability of project benefits is likely. The RF has stopped proving quotas for imports of CFC, and no more CFC containing Salbutamol MDIs are being produced, since 2015. Despite initial resistance from patients and even a member of the Russian Academy of Medical Sciences, the patients will have to buy what is available in the market, according to need and affordability.

Regarding institutional framework and governance risks, the sustainability of project benefits is likely. The project responded to a request for support by RF to stop using CFCs, and fulfill its obligations towards Montreal protocol. Therefore, it is very unlikely that this process gets reverted.

Regarding environmental risks, the sustainability of project benefits is likely. The project is considered to be ecologically sound and sustainable as it has allowed to *phase-out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered- Dose Inhalers (MDIs) in the Russian Federation (RF), and to reduce future GHG emissions by approx. 1.7*

MMT CO_2 t/equivalent, by introducing, a lower GHG propellant emission. HFC134 has a medium global warming potential. Currently research is undergoing worldwide[14] to find a replacement for HFC134 with lower GWP.

In conclusion, the rating on sustainability of project benefits is **Likely**.

3.7. Gender mainstreaming

Gender[15] and women's empowerment was not featured prominently in the design and implementation of the project. At the time of project formulation gender was not a requirement of GEF. UNIDO had just started its gender policy - *UNIDO's Policy on Gender Equality and the Empowerment of Women*, was issued in 2009.

Women have been involved in the project, as beneficiaries (reportedly women, who make up 68% of the adult patients suffering from asthma in RF) or project players (there are women in factories' management positions, and in authority or high position). But by itself that does not mean that the project addressed gender issues. The evaluation team could not find evidence that the project would have been different if most asthma patients would be men, or in which way has the project contributed to gender balance on employment and high rank positions occupied by women.

As the project was mostly concerned with the provision of the production lines for HFA-based Salbutamol MDI production, the evaluation team asked the factories directly if the new production lines brought some change in gender. The answer was that women will continue mostly engaging in quality control and packaging (factories management consider women are in general more focused and attentive to details and are more suitable for quality control work). Men will continue to do the heavier part of the work, on feeding the production line.

Rating on gender mainstreaming is **Unsatisfactory**.

3.8. Assessment of monitoring and evaluation systems

As stated previously, the proposed monitoring and evaluation (M&E) plan was very generic, and it was supposed to be implemented with the support of the HCFC Phase-out project.

The project document referred that a Project Steering Committee (PSC) would be formed at the inception stage of the project. The PSC should meet twice a year and be responsible for the overall strategic and policy guidance of the project. A detailed schedule of project reviews should have been developed by the project management team, in consultation with project implementation partners and representatives of the participating communities (for example, Russian Lung Association, etc.), during the early stages of project initiation. Such a schedule would include tentative timeframes for PSC meetings, and monitoring and

[14] Myrdal PB, Sheth P, Stein SW. Advances in metered dose inhaler technology: formulation development. AAPS PharmSciTech. 2014;15(2):434-55.

[15] Russia's gender equality index is 0.338 placing it 49th out of 188 countries (UNDP, 2016).

evaluation of the project activities by the PSC. There was no PSC and the schedule of project reviews has not been developed.

No budget has been allocated to M&E plan. The Project Document suggested that, in order to use funds efficiently, the MDI Project could be monitored by the Project Monitoring Unit (PMU) established for the HCFC Phase out project, especially by organizing annual PSC meetings. In reality there has been limited communication between the two projects at country (RF) level and the PMU of HCFC-Phase Out was not instructed to participate in M&E of the MDI project. The Project Document also suggested that UNIDO ITPO office in Moscow would monitor this project implementation. In reality UNIDO ITPO office in Moscow was not mandated to perform monitoring and its action was limited to logistic support to UNIDO HQ-PMU and helping with customs clearance to Altayvitaminy.

The yearly project implementation reports have been produced and submitted to GEF. The reports mirror the fact that, the PMU did follow mostly purchasing and installation of the production lines. The PIR 2016 refers generically Altayvitaminy's progress on registration of the new Salbutamol and PIR 2017 reports Altayvitaminy start of production. No details can be found in the PIRs on the components 1, 3 and 4.

The last visit of UNIDO PM to the project was implemented in January 2017, but no report has been provided to the evaluation team. It is known from further communication between UNIDO and the MNRE that the UNIDO PM did not contact the MNRE at the time of the visit.

It is also to be noticed that according to official UNIDO communication, due to the budget constraints, UNIDO's Evaluation Office suggested to conduct joint terminal evaluations together of this Project with the other HCFC Phase Out project. Budget allocation to the evaluation of the project has been adequate.

Rating on M&E is **Unsatisfactory.**

3.9. Results Based Management

As referred throughout the previous sections, the UNIDO HQ-based management, coordination, monitoring, quality control and technical inputs were limited. As the GEF grant could only cover the purchase of the production lines, UNIDO PM did not follow Components 1, 3 and 4 of the project. There have been several changes in Project Manager during the implementation, and some of the previous PMs left UNIDO without properly passing the implementation-related information to their successors. At the beginning of the evaluation and during field mission the then-PM could provide only very reduced information about the project, see Chapter 1, page 3.

There were conditions for some sort of national management support, but it has not been used by UNIDO-HQ PM. At the beginning of the project, UNIDO PM and MNRE - as focal point of GEF and Montreal Protocol - had assigned roles and responsibilities. However, MNRE received the last report of the project in 2015, and was under the impression that the project ended at that time - MNRE did not receive copies of the 2015 and 2016 yearly reports to GEF. The Ministry of Health did not follow the project. At the beginning of the project

Roszdravnadzor has been informed about the planned implementation of production lines for the manufacture of CFC-free MDIs. The evaluation team could not meet with the Ministry of Health despite of several attempts, and Roszdravnadzor representative told the evaluation team it was not possible to find any person who could talk to the team about the project.

The beneficiary companies kept the contact with MNRE. MNRE provided support on some administrative issues, such as tax exemptions. MNRE learned about the last visit of UNIDO-HQ PM from the beneficiary companies, as no meeting was held with MNRE. MNRE also participated in the Steering Committee meetings of the HCFC Phasing out project.

The results-based management is considered **Moderately Unsatisfactory**.

3.10. Performance of Partners

Selection of the technology supplier was done through a transparent process by UNIDO, with the involvement of the different stakeholders including by the beneficiary companies. Up to 2015, UNIDO has provided support to address implementation bottlenecks on the production lines set up and installation.

The international supplier hired by UNIDO performed well and with interest in the project. The supplier was resilient through the several delays the project has had, which were due to the beneficiary companies. The supplier knows that companies have to keep the PAMASOL line for 5 years, and expects to keep in contact with both companies, in particular regarding spare parts orders, requests for technical support or similar. The supplier is aware that Altaivitaminy is more advanced in the process of producing the new MDI, as sometimes get technical questions about the operation of the line.

UNIDO has also not assumed a Coordination function regarding the different components of the project. As seen above, the project did not use UNIDO's country presence as foreseen in the project document. The two projects did not communicate as they should and no information on the implementation of Component 1 can be found on the PIRs.

Country ownership of the project results is high, in particular by the beneficiary companies. Both have invested a significant amount of funds and efforts to start producing the new MDIs. MNRE did follow the project, and provided some support when it has been requested, but did not have a pro-active role on following the project implementation.

It is also to be noticed that RF authorities completely phased out use of CFC for medical purposes. The evaluation team could not get anyone at the Ministry of Health or Roszdravnadzorwho to talk about the project. This indicates that ownership of the project by other stakeholders is limited.

GEF did provide funding as foreseen, however it took two and half years between project document submission and the grant being available. It is not clear if GEF has provided feedback to the yearly reports.

The performance of the partners is considered **Moderately Satisfactory**.

3.11. Overall Project Achievement

Table 3 below summarizes the evaluators' assessment of the project

Evaluation Criteria	Comments	Rating
Progress to impact	As the beneficiary companies are still not producing the new ODS-free Salbutamol MDIs on a regular basis, it is not possible to assess progress to impact of the project. However, the MNRE ceased providing quotas for CFC imports and patients have access to Salbutamol.	MS
Project design		MS
Overall design	The project design was adequate to address the problems, and consistent with the country and donors priorities. Stakeholder analysis had some limitations and some risks were not adequately addressed. The objective could have been more focused on the actual project, as part of the objective is an obligation that RF had to comply with independently of the project.	MS
Logframe	The PRF was limited to outputs and activities. There are no indicators for outcomes and objectives.	MU
Project performance		S
Relevance	The project is highly consistent with RF and GEF objectives of stop using CFC. The project is based on UNIDO experience with several MDI conversion processes worldwide since 2006.	HS
Effectiveness	The project grant budget ended being sufficient only to cover component 2. UNIDO was not involved in any activities on component 3 and 4. UNIDO through the project HCFC Phase-out performed some of the activities of component 1.	MS
Efficiency	The project was supposed to end in January 2014, but the last activities (site acceptance test at Moschimpharmpreparaty) occurred in October 2017. The financial resources were not sufficient for the project to implement all activities.	MU
Sustainability of benefits	The new production lines for ODS-free Salbutamol MDIs are installed and nearly ready to start normal production. Then it will be normal functioning of the markets. The RF has ceased to provide quotas for the import of CFCs. At the time of the evaluation, the two beneficiary companies nearly exhausted their stocks of the CFC-containing Salbutamol	Likely

Evaluation Criteria	Comments	Rating
	MDIs.	
Cross-cutting performance criteria		U
Gender mainstreaming	The project did not address gender mainstreaming	U
M&E design and implementation	M&E was very generic and was based on the support from UNIDO ITPO office in Moscow and the HCFC Phase out project, which UNIDO-HQ did not materialize.	U
Results-based Management (RBM)	The approach agreed for the project was not followed. The project benefitted from experienced and interested technology supplier. Country ownership is satisfactory, from the side of beneficiary companies, but not leadership from national entities. Financial and backstopping support from UNIDO was less than satisfactory.	MU
Performance of partners		MS
UNIDO	UNIDO PM provided adequate and timely supervision and backstopping to the project implementation until 2015. However this has been limited to component 2 activities.	MU
National counterparts	The beneficiary companies adhered to the project, although originating delays (particularly Moschimpharmpreparaty). MNRE provided support whenever they have been called into action.	MS
Donor	GEF provided funds but it took long time (2.5 years) between submission of project document and funds available. It is not clear if GEF provided comments to the project implementation reports.	MS
Overall assessment		MS

Project rating criteria[16]

Score		Definition	Category
6	Highly satisfactory	Level of achievement clearly exceeds expectations and there is no shortcoming.	SATISFACTORY

[16] The Project rating criteria are those of the ToR which are different from those of the UNIDO's Evaluation Manual, 2018. Actually the rating would be higher according to UNIDO evaluation manual.

5	Satisfactory	Level of achievement meets expectations (indicatively, over 80-95 per cent) and there is no or minor shortcoming.	
4	Moderately satisfactory	Level of achievement more or less meets expectations (indicatively, 60 to 80 per cent) and there are some shortcomings.	
3	Moderately unsatisfactory	Level of achievement is somewhat lower than expected (indicatively, less than 60 per cent) and there are significant shortcomings.	UNSATISFACTORY
2	Unsatisfactory	Level of achievement is substantially lower than expected and there are major shortcomings.	
1	Highly unsatisfactory	Level of achievement is negligible and there are severe shortcomings.	

Project rating criteria for sustainability:

Score		**Definition**
6	Likely (L)	There are no risks affecting this dimension of sustainability.
5 or 4	Moderately Likely (ML)	There are moderate risks that affect this dimension of sustainability.
3 or 2	Moderately Unlikely (MU)	There are significant risks that affect this dimension of sustainability
1	Unlikely (U)	There are severe risks that affect this dimension of sustainability

IV. Conclusions, recommendations and lessons learned

4.1 Conclusions

The project *Phase-out of CFC consumption in the manufacture of aerosol metered dose inhalers (MDIs) in the Russian Federation,* funded by the Global Environment Facility (GEF) was implemented from March 2012 to March 2018 by the United Nations Industrial Development Organization (UNIDO), and the two factories that produced CFC-containing Salbutamol MDI. The main national partner of the project was the Ministry of Natural Resources and Environment (MNRE). The project had two main objectives*:* (a) through appropriate technology transfer, to phase-out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation; and (b) to reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer, a lower GHG propellant.

This project is Highly Relevant as it supports the compliance of RF with the Montreal Protocol (MP) obligation of phasing out production and consumption of CFCs, while providing the required technical assistance to convert the production of CFC-based metered-dose inhalers (MDIs) to ozone-friendly HFC-134a at the two national companies producing Salbutamol MDI, a lifesaving drug. The proposed project is consistent with GEF Focal Area Objective CHEM-2: “Phase out of Ozone Depleting Substances (ODS)”, Outcome 2.2 “Ozone Depleting Substances”, Output 2.2.1 is 212 MT of CFCs.

The project received substantial co-financing from the benefiting companies, which is in line with GEF’s additionally or so-called incremental approach principles. The GEF incremental funding enabled technology transfer that speeded up the process of developing and obtaining approvals for a CFC-free MDI replacement, contributing to the RF’s compliance with the Montreal Protocol obligation of total phase out of CFC consumption, without impacting the availability of MDI Salbutamol in the RF market.

Effectiveness of the project is considered **Moderately Satisfactory**. The two companies have installed the production lines and have already produced and sold the new formulation of Salbutamol MDIs. This means that both companies installed the production lines and prepared the necessary infrastructure for the lines to operate (works had to be performed in the rooms containing the lines and adjacent rooms), and both have successfully passed the Site Acceptance Test (SAT). This also means that the new Salbutamol formulations have been developed and registered. The RF has stopped proving quotas for imports of CFCs since 2015, and no more CFC containing Salbutamol MDIs are being produced. The objective of the project will be achieved when the two plants start mass-producing the new CFC-free Salbutamol MDI.

Efficiency is rated **Moderately Unsatisfactory.** The project started in January 2012, and was initially planned to be completed within 24 months (December 2014). However, only in October 2017 the project finally came to an end with the last activities completed. Besides, not all results were achieved within the original budget. The two purchase orders to equipment supplier PAMASOL amounted to

USD 2,521,395, using all GEF grant and cutting-off part of the UNIDO project management costs of USD 50,000 allocated in The Project Document (PD). Although the difference between the estimate at project preparation and the actual cost is less than 10%, the impact turned out significant due to the reduced budget for other activities. Some of the activities of information/sensitization (Component 1), and technical assistance envisioned in Components 3 and 4 have not been performed. Part of activities under Component 1 were implemented by another project, and not accompanied by the PM of the project under evaluation.

Results based management and UNIDO performance were both **Moderately Unsatisfactory**. The approach originally agreed upon by stakeholders for the implementation was not followed. In particular, there was no steering committee and no local project co-management or monitoring - as UNIDO ITPO office[17] ended up not being mandated to follow up the project. The potential synergies with the HCFC Phase Out project were limited to a conference prior to the start of the project - this despite of the fact that HCFC Phase

Out project implemented part of the activities of Component 1 (which were also on its own project document). UNIDO PM provided adequate and timely supervision and backstopping to the project implementation until 2015, but limited to Component 2 activities. According to the UNIDO PM at the time of implementation "*contrary to the PD, no activities under Components 1, 3 and 4 could be paid from the GEF grant and hence these activities had to be fully covered by co-financing. That is why UNIDO was not involved in any activities on component 3 and 4.*"

Country ownership from the side of beneficiary companies is **Moderately Satisfactory**. Leadership from national authorities was less than satisfactory. In communication with UNIDO in 2018, MNRE reports the latest update received on the projects dated 2015. MNRE thought that the project had ended then and did not seek further information. UNIDO PM did not communicate with MNRE in the course of the January 2017 mission

The sustainability of the results is rated **Likely**. The RF has ceased to provide quotas for the import of CFCs. At the time of the evaluation, the two beneficiary companies nearly exhausted their stocks of the CFC-containing Salbutamol MDIs. Both companies have already produced and sold in the market the new Salbutamol MDI formulation.

Altayvitaminy referred that normal commercial production of the new MDI would start in June 2018, while Moschimpharmpreparaty reported that the line would be in normal production by November 2018[18]. Further sustainability will depend on the capabilities of the two beneficiary companies to produce and commercialize the ODS-free Salbutamol MDIs on a competitive market basis, at affordable

[17] ITPO Russian Federation was established in 1989. It is different from a country office. Its mandate is to promote international cooperation in the economic, technological, industrial and scientific spheres between Russian enterprises, associations and organizations and firms from developed and developing countries. UNIDO ITPO office is sometimes called to support project implementation.

[18] At the time of evaluation the two lines were idle due to annual maintenance and repair of the factories.

prices to patients, and of the generalized acceptance[19] by patients of the new formulation.

4.2 Recommendations

The evaluation team recommends the following:

To UNIDO:	
R1	In future similar projects in Russia ensure further coordination at country level, in particular when there are projects and/or local UNIDO offices dealing with projects of similar scope.
R2	In future projects, when introducing new drug formulation due to environmental issues, it should be ensured a better financial planning and adequate funding for awareness activities to explain patients and medical service staff what will happen and why. This may ensure a smoother transition and acceptance of the new drug.
R3	In future projects, including new technology transfer, further efforts should be made to conciliate as much as possible needs and expectations of each beneficiary company (it can be slightly different from company to company) with the rules and procedures of UNIDO procurement, and to agree upon commitments of the companies themselves, defining penalties for non-compliance. This can limit delays and promote channeling of funds to activities that companies may have more difficulties in covering.
R4	UNIDO should enforce requirements and documented procedures to ensure full handover of project-related information in case of change of project managers (PM).

19 Companies hav been receiving complaints from patients of sour throat when using the new Salbutamol MDIs.

4.3 Lessons learned

Lessons emerged from this project:
1. There is lack of information regarding key decisions/agreements occurring during project implementation, namely on which components should be supported by the grant, which should be implemented by co-funding, and which to drop. *It is important to report/document key decisions and agreements occurring during project implementation for future reference, and in particular as PM and beneficiary representatives often change.*
2. The limitations of the evaluation, namely the lack of institutional memory of project in UNIDO Headquarters, showcase the *need for a good information transfer when UNIDO PM changes occur.*
3. The project document highlighted synergies with the HCFC Phase out in the Russian Federation Project, namely regarding steering committee meetings, and stated UNIDO ITPO office in Moscow would monitor the project. These synergies were not explored. Even the coinciding activities (namely at component 1 of MDI project) that HCFC Phase out project implemented were not taken as part of the MDI project (ex. not reported in the Project Implementation Report, PIR, to GEF). Opportunities were lost of improved implementation, visibility, and stakeholder involvement in the MDI project. Lack of information at country level has also impacted the evaluation. *It is important to seek more synergies between UNIDO projects occurring simultaneously on related topics, and to benefit from the presence in the country to accompany the beneficiaries and project implementation whenever there is opportunity*.
4. Part of the large delay in the project implementation was due to lack of final agreement between beneficiary companies and equipment supplier, and requests for changes in equipment specifications. Both beneficiary companies report they would have liked to have more freedom to decide what they want, and would be ready to pay the difference. *When working directly with companies it is important to make it clear upfront for the companies the limitations imposed by UNIDO procurement, and to negotiate with each company how to apply the grant funds. It is also important to define well the roles and responsibilities of each stakeholder and set consequences of non-compliance. UNIDO technical mediation on the negotiations between technology supplier and the beneficiary companies can be very useful.*

Lessons emerged from this project:
5. The activities foreseen in Component 1 such as training for doctors, pharmacists, lung specialists on the new HFA MDIs techniques including the details of new therapy; and awareness and communication to public relations officers at the Ministries on the ban of CFC use in the RF (namely on ministry of Health) were not conducted. The beneficiary companies consider this one of the major weaknesses of the project, due to many complaints and disinformation existing on the new MDI Salbutamol product. *Information campaign[20] (implemented by authorities and/or associations with the participation or not of the companies) should not be dropped in projects introducing new formulations in crucial medicines. Those information campaigns may generate space for useful debate (ex. online).*
6. In case of technology transfer projects where majority of funding is meant for purchase of equipment, application of the rule that allows to change any of the budget lines by up to 10% may have a drastic effect of the project implementation. About 90% of the GEF grant for the evaluated project was earmarked for the purchase of the MDI filling lines, and 9.6% increase in this budget line almost completely exhausted the GEF grant. As a result, a number of other planned activities, e.g. information campaign, were not implemented. To address this issue UNIDO may consider including a Contingency reserve when developing the project budgets (e.g. 5-7% of the project budget) to mitigate the possible increase in the equipment cost in the course of the project implementation without seriously depleting budget lines for other activities.
7. When implementing projects in which other ministries are also involved it is important to MNRE to keep a good dialogue, to be able to follow up the evolution of the activity, and to establish synergies and common actions (ex. awareness raising, information).
8. It is important to increase MNRE participation in projects monitoring and/or accountability/reporting to project implementation agencies, to avoid the existence of “dormant/phantom” projects

[20] See for example: https://www.fda.gov/Drugs/ResourcesForYou/ucm083011.htm; https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm077808.htm#How_different; https://www.news-medical.net/news/2008/11/10/42654.aspx; https://assets.nationalasthma.org.au/resources/183-information_statement_for_health_professionals.pdf

Annexes

Annex I – Terms of Reference

D R A F T

TERMS OF REFERENCE

Independent terminal evaluation of project

UNIDO project ID: 100352
GEF Project ID: 4387

January 2018

Contents

I. PROJECT BACKGROUND AND CONTEXT

1. Project factsheet[21][22]

Project title	[Title]
UNIDO project ID	100352
GEF Project ID	4387
Region	Europe and Central Asia (EUR)
Country(ies)	[Keywords]
Project donor(s)	GEF
Project implementation start date	[Publish Date]
Expected duration	24 months
Expected implementation end date	31 March 2018
GEF Focal Areas and Operational Project	Ozone Depletion Substances
Implementing agency(ies)	UNIDO
Government coordinating agency	Ministry of Natural Resources and Environment (MNRE) (through the Ozone Unit)
Executing Partners	Ministry of Natural Resources and Environment
UNIDO RBM code	GC33 (Implementation of MEA)
Donor funding	USD 2,550,000 (excluding PPG)
Project GEF CEO endorsement / approval date	12/15/2008
UNIDO input (in kind, USD)	In kind 50,000
Co-financing at CEO Endorsement, as applicable	Total expected: USD 5,600,000 MEP (cash & in-kind) MOF (cash) Local EPBS (cash & in-kind) Pesticides owners and other private sectors (cash & in-kind)
Planned terminal evaluation date	February – March 2018

(Source: Project document)

2. Project context

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-

[21] Data to be validated by the Consultant

[22] Different data for implementation start date: July 2009 according to mid-term review and October 2011 according to UNIDO Open Data Platform as of August 2017

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 chlorofluorocarbons-11 (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 still required to convert the production of CFC metered-dose inhalers (MDIs) to ozone-friendly hydrofluorocarbons (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 was not yet fulfilled because funds were not available at the time to assist in this conversion.

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 now produced by the two Russian enterprises, i.e. «Altayvitaminy Ltd. », Biysk, Altay region and Federal State Enterprise «MosChimPharmPreparaty», Moscow. These two MDI producers are still consuming annually about 212 MT of CFC-11 (solvent) and CFC-12 (propellant) (2010) needed for MDI 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 Russian Federation by the end of 2012.
Decision XXI/4(8) of the Meeting of the Parties (MOP) requested the Technology and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC) 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 recommendation of the TEAP was that financial support is the main priority and GEF funding should be investigated urgently as the first option since finance governs the success of the transition in the Russian Federation. Based on the TEAP/MTOC mission, the Parties could expect that 18-24 months would be the overall time for conversion of the two enterprises once funding is approved by the implementing agency.

3. Project objective and expected outcomes

The objectives of this project are (a) through appropriate technology transfer, to phase out the consumption of 212 ODP tones of CFC-11 and CFC-12 (2010) used in the manufacture of Aerosol Metered-Dose Inhalers (MDIs) in the Russian Federation (RF); and (b) to reduce future GHG emissions by approx. 1.7 MMT CO_2 t/equivalent, by introducing, through technology transfer, a lower GHG propellant.

The two MDI companies in the RF required technology transfer from one, or more, established multinational enterprises with experience in the development and manufacture of MDIs using CFC-free technologies, and with 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.

This project aimed at addressing the requirements for conversion of a manufacturing facility currently using CFCs to manufacture MDIs with CFC-free propellant.

The project includes four major components:

Component 1. Institutional and regulatory capacity building for ODS phase out

Expected outcomes include (i) Policies reviewed and CFC legislation improved, if necessary; (ii) ODS and CFC import/export legislation updated to reflect final phase out of CFCs in MDIs.

Component 2. Phase out of CFC consumption -212 MT (2010) in the Medical aerosol (MDI) sector at two

Russian enterprises

Expected outcomes include (i) meeting Montreal Protocol phase out obligations (Phase out of 212ODP tonnes of CFC(CFC-11 and CFC12)); and (ii) Technical assessment of production capacity within the MDI sector,

Component 3. Technology transfer in developing a new HFA –based MDI

The expected outcome is that new MDI products meeting national and internationals standards are designed and developed.

Component 4. New developed MDIs registered at the Ministry of Health and Social Development.

The expected outcome is that the new MDI products are registered at the Ministry of Health for use.

Component 5. Project management, monitoring and evaluation.

These outcomes were planned to be achieved through the production of 17 outputs.

4. Project implementation arrangements

The Ministry of Natural Resources and Environment is responsible for the total CFC phase out in the RF and it has been involved in execution of the ODS Phase-out Programme of the RF. The Ministry of Health and Population is the on-line Ministry to which the two Russian MDI enterprises are subordinated. This Ministry is responsible for the final conversion of CFC-based MDI production to CFC-free MDI production at the two Russian enterprises, subject of this project, and for all necessary arrangements associated with control and monitoring of CFC-free MDI imports into the country.

The project management structure as designed is provided in Figure 1.

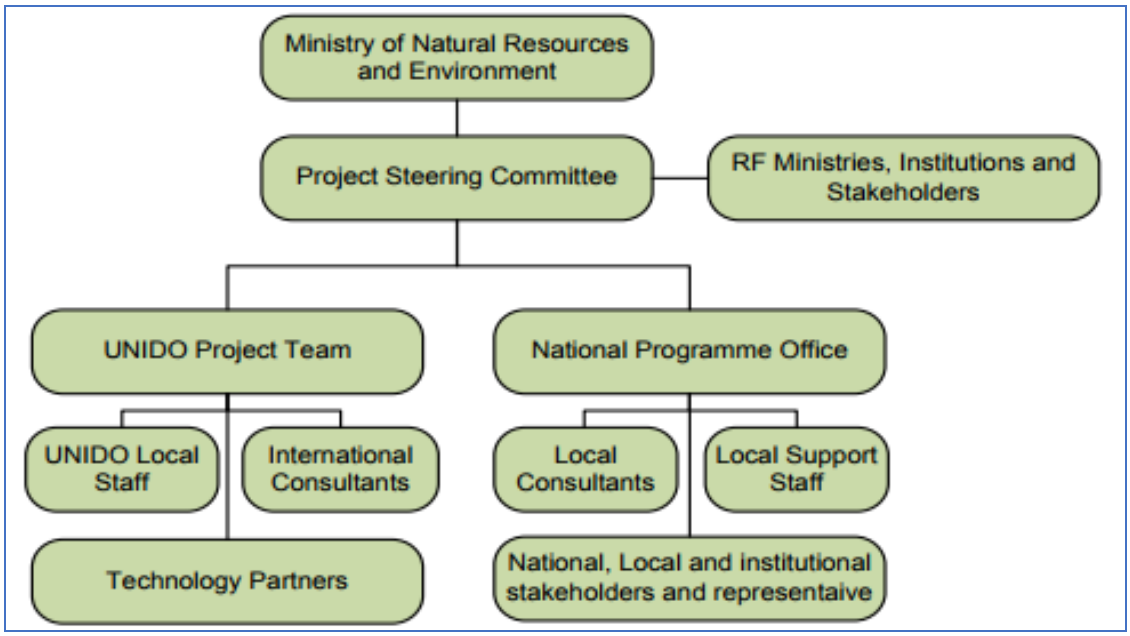

Figure 1. Project Organogram

A Project Steering Committee (PSC) was to be formed at the inception stage of the project, due to meet twice a year and be responsible for the overall strategic and policy guidance of the Project.

In order to use efficiently funds, the Project was to be monitored by the Project Monitoring Unit (PMU) established for the HCFC Phase out Project in the Russian Federation, especially in organizing annual PSC meetings.

The UNIDO office in Moscow was to be the coordinator of the whole GEF programme in the RF including the monitoring this project implementation.

5. Budget information

Table 1. Financing plan summary

Description	**Project Preparation**	**Project**	**Total** (USD)
Financing (GEF / others)	Click here to enter text.	2,550,000	2,550,000
Co-financing (Cash and In-kind)	Click here to enter text.	5,600,000	5,600,000
Total (USD)	Click here to enter text.	**8,150,000**	**8,150,000**

Source: Project document

Table 2. Financing plan summary - Outcome breakdown[23]

Project outcomes	**Donor** (GEF/other) (USD)	**Co-Financing** (USD)	**Total** (USD)
1.1 and 1.2. Policies reviewed and CFC legislation improved, if necessary; ODS and CFC import/export legislation updated to reflect final phase out of CFCs in MDIs.	50,000	100,000	**150,000**
2.1 and 2.2 To meet Montreal Protocol phase out obligations(Phase out of 212ODP tonnes of CFC(CFC-11 and CFC12)); Technical assessment of production capacity within the MDI sector	2,300,000	4,700,000	**7,000,000**
3.1. Design and development of new MDI products that meet national and international standards	100,000	500,000	**600,000**
4.1. New MDI products registered at the Ministry of Health for us	50,000	200,000	**250,000**
5. Project management	50,000	100,000	**150,000**
Total (USD)	**2,550,000**	**5,600,000**	**8,150,000**

Source: Project document

Table 3. Co-Financing source breakdown

Name of Co-financier (source)	**In-kind**	**Cash**	**Total Amount** (USD)
UNIDO	50,000	50,000	100,000
Private sector (Two pharmaceutical companies in the RF: MosChimPharmPreparaty, Moscow and Altayvitaminy Ltd., Biysk, Altay region)	5,500,000		5,500,000
Total Co-financing (USD)	5,550,000	50,000	5,600,000

Source : Project document

[23] Source: Project document.

Table 4. UNIDO budget execution (Grant 200000310)

Item of expenditure	2012	2013	2014	2015	2016	2017	2018	Total expend.
Contractual Services								
Equipment		252,140	2,269,256	0	0	0		2,521,395
Nat. Consult./Staff	17,392							17,392
Other Direct Costs				97	0			97
Staff & Intern Consultants			2,725	-399				2,326
Grand Total	**17,392**	**252,140**	**2,271,981**	**-302**	**0**	**0**		**2,541,210**

Source: UNIDO. ERP database as of 26 January 2018

II. Scope and purpose of the evaluation

The terminal evaluation (TE) will cover the whole duration of the project from its starting date in to the estimated completion date in 3/31/2018. It will assess project performance against the evaluation criteria: relevance, effectiveness, efficiency, sustainability and impact.

The TE has an additional purpose of drawing lessons and developing recommendations for UNIDO and the GEF that may help for improving the selection, enhancing the design and implementation of similar future projects and activities in Russian Federation and on a global scale upon project completion. The TE report should include examples of good practices for other projects in the focal area, country, or region.

The TE should provide an analysis of the attainment of the project objective and the corresponding technical outputs and outcomes. Through its assessments, the Evaluation Team (ET) should enable the Government, counterparts, UNIDO, the GEF and other stakeholders and donors to verify prospects for development impact and sustainability, providing an analysis of the attainment of global environmental objectives, project objectives, delivery and completion of project outputs/activities, and outcomes/impacts based on indicators. The assessment shall include re-examination of the relevance of the objectives and other elements of project design according to the project evaluation parameters defined in chapter 0.

The key question of the TE is whether the project has achieved or is likely to achieve its main objective, i.e.

The evaluation has three specific objectives:

(i) Assess the project performance in terms of relevance, effectiveness, efficiency, sustainability and progress to impact;
(ii) Identify key learning to feed into the design and implementation of the forthcoming projects; and
(iii) Develop a series of findings, lessons and recommendations for enhancing the design of new and implementation of ongoing projects by UNIDO.

III. Evaluation approach and methodology

The TE will be conducted in accordance with the UNIDO Evaluation Policy[24] and the UNIDO Guidelines for the Technical Cooperation Project and Project Cycle[25]. In addition, the GEF Guidelines for GEF Agencies in Conducting Terminal Evaluations, the GEF Monitoring and Evaluation Policy and the GEF Minimum Fiduciary Standards for GEF Implementing and Executing Agencies will be applied.

The evaluation will be carried out as an independent in-depth evaluation using a participatory approach whereby all key parties associated with the project will be informed and consulted throughout the evaluation. The evaluation team leader will liaise with the UNIDO Independent Evaluation Division on the conduct of the evaluation and methodological issues.

In line with its objectives, the evaluation will have two main components. The first component focuses on an overall **assessment of performance** of the project, whereas the second one focuses on the **learning** from the successful and unsuccessful practices in project design and implementation.

The evaluation will use a theory of change approach and mixed methods to collect data and information from a range of sources and informants. It will pay attention to triangulating the data and information collected before forming its assessment. This is essential to ensure an evidence-based and credible evaluation, with robust analytical underpinning.
The theory of change will identify causal and transformational pathways from the project outputs to outcomes and longer-term impacts, and drivers as well as barriers to achieve them. The learning from this analysis will be useful to feed into the design of the future projects so that the management team can effectively manage them based on results.

1. Data collection methods

Following are the main instruments for data collection:

(a) **Desk and literature review** of documents related to the project, including but not limited to:
- The original project document, monitoring reports (such as progress and financial reports, mid-term review report, output reports, back-to-office mission report(s), end-of-contract report(s) and relevant correspondence.
- Notes from the meetings of committees involved in the project.

(b) **Stakeholder consultations** will be conducted through structured and semi-structured interviews and focus group discussion. Key stakeholders to be interviewed include:
- UNIDO Management and staff involved in the project; and
- Representatives of donors, counterparts and stakeholders.

(c) **Field visit** to project sites in the Russian Federation.

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[24] UNIDO. (2015). Director General's Bulletin: Evaluation Policy (UNIDO/DGB/(M).98/Rev.1)

[25] UNIDO. (2006). Director-General's Administrative Instruction No. 17/Rev.1: Guidelines for the Technical Cooperation Programme and Project Cycle (DGAI.17/Rev.1, 24 August 2006)

2. Evaluation key questions and criteria

The key evaluation questions are the following:

(a) What are the key drivers and barriers to achieve the long-term objectives? To what extent has the project helped put in place the conditions likely to address the drivers, overcome barriers and contribute to the long-term objectives?

(b) How well has the project performed? Has the project done the right things? Has the project done things right, with good value for money?

(c) What have been the project's key results (outputs, outcome and impact)? To what extent have the expected results been achieved or are likely to be achieved? To what extent the achieved results will sustain after the completion of the project?

(d) What lessons can be drawn from the successful and unsuccessful practices in designing, implementing and managing the project?

The evaluation will assess the likelihood of sustainability of the project results after the project completion. The assessment will identify key risks (e.g. in terms of financial, socio-political, institutional and environmental risks) and explain how these risks may affect the continuation of results after the project ends. Table 5 below provides the key evaluation criteria to be assessed by the evaluation. Detailed questions to assess each evaluation criterion are provided in annex 2.

Table 5. Project evaluation criteria

#	Evaluation criteria	Mandatory rating
A	**Impact**	**Yes**
B	**Project design**	**Yes**
1	• Overall design	Yes
2	• Logframe	Yes
C	**Project performance**	**Yes**
1	• Relevance	Yes
2	• Effectiveness	Yes
3	• Efficiency	Yes
4	• Sustainability of benefits	Yes
D	**Cross-cutting performance criteria**	
1	• Gender mainstreaming	Yes
2	• M&E: ✓ M&E design ✓ M&E implementation	Yes
3	• Results-based Management (RBM)	Yes
E	**Performance of partners**	
1	• UNIDO	Yes
2	• National counterparts	Yes
3	• Donor	Yes
F	**Overall assessment**	Yes

3. Rating system

In line with the practice adopted by many development agencies, the UNIDO Independent Evaluation Division uses a six-point rating system, where 6 is the highest score (highly satisfactory) and 1 is the lowest (highly unsatisfactory) as per Table 6.
Table 6. Project rating criteria

Score		Definition	Category
6	Highly satisfactory	Level of achievement clearly exceeds expectations and there is no shortcoming.	SATISFACTORY
5	Satisfactory	Level of achievement meets expectations (indicatively, over 80-95 per cent) and there is no or minor shortcoming.	
4	Moderately satisfactory	Level of achievement more or less meets expectations (indicatively, 60 to 80 per cent) and there are some shortcomings.	
3	Moderately unsatisfactory	Level of achievement is somewhat lower than expected (indicatively, less than 60 per cent) and there are significant shortcomings.	UNSATISFACTORY
2	Unsatisfactory	Level of achievement is substantially lower than expected and there are major shortcomings.	
1	Highly unsatisfactory	Level of achievement is negligible and there are severe shortcomings.	

IV. Evaluation process

The evaluation will be conducted from February to March 2018. The evaluation will be implemented in five phases which are not strictly sequential, but in many cases iterative, conducted in parallel and partly overlapping:

i. Inception phase: The evaluation team will prepare the inception report providing details on the methodology for the evaluation and include an evaluation matrix with specific issues for the evaluation; the specific site visits will be determined during the inception phase, taking into consideration the findings and recommendations of the mid-term review.
ii. Desk review and data analysis;
iii. Interviews, survey and literature review;
iv. Country visits;
v. Data analysis and report writing.

V. Time schedule and deliverables

The evaluation is scheduled to take place from February to April 2018. The evaluation field mission is tentatively planned during March 2018. At the end of the field mission, there will be a presentation of the preliminary findings for all stakeholders involved in this project.

After the evaluation field mission, the evaluation team leader will visit UNIDO HQ for debriefing and presentation of the preliminary findings of the terminal evaluation. The draft TE report will be submitted 4 to 6 weeks after the end of the mission. The draft TE report is to be shared with the UNIDO PM, UNIDO Independent Evaluation Division, the UNIDO GEF Coordinator and GEF OFP and other stakeholders for receipt of comments. The ET leader is expected to revise the draft TE report based on the comments received, edit the language and form and submit the final version of the TE report in accordance with UNIDO Independent Evaluation Division standards.

Table 7. Major timelines

Timelines	**Tasks**
February 2018	Desk review and writing of inception report
February 2018	Vienna: briefing with HQ
March 2018	Field visit
March/April 2018	Debriefing in Vienna Preparation of first draft evaluation report
April 2018	Internal peer review of the report by UNIDO's Independent Evaluation Division and other stakeholder comments to draft evaluation report
April 2018	Final evaluation report

VI. Evaluation team composition

The evaluation team will be composed of one international evaluation consultant acting as the team leader and one national evaluation consultant. The evaluation team members will possess relevant strong experience and skills on evaluation management and conduct together with expertise and experience in innovative clean energy technologies. Both consultants will be contracted by UNIDO.

The tasks of each team member are specified in the job descriptions annexed to these terms of reference. The ET is required to provide information relevant for follow-up studies, including terminal evaluation verification on request to the GEF partnership up to three years after completion of the terminal evaluation.

According to UNIDO Evaluation Policy, members of the evaluation team must not have been directly involved in the design and/or implementation of the project under evaluation.

The UNIDO Project Manager and the project team in the Russian Federation will support the evaluation team. The UNIDO GEF Coordinator and GEF OFP(s) will be briefed on the evaluation and provide support to its conduct. GEF OFP(s) will, where applicable and feasible, also be briefed and debriefed at the start and end of the evaluation mission.

An evaluation manager from UNIDO Independent Evaluation Division will provide technical backstopping to the evaluation team and ensure the quality of the evaluation. The UNIDO Project Manager and national project teams will act as resourced persons and provide support to the evaluation team and the evaluation manager.

VII. Reporting

Inception report

This Terms of Reference (ToR) provides some information on the evaluation methodology, but this should not be regarded as exhaustive. After reviewing the project documentation and initial interviews with the project manager, the International Evaluation Consultant will prepare, in collaboration with the national consultant, a short inception report that will operationalize the ToR relating to the evaluation questions and provide information on what type of and how the evidence will be collected (methodology). It will be discussed with and approved by the responsible UNIDO Evaluation Manager.

The Inception Report will focus on the following elements: preliminary project theory model(s); elaboration of evaluation methodology including quantitative and qualitative approaches through an evaluation framework ("evaluation matrix"); division of work between the International Evaluation Consultant and national consultant; mission plan, including places to be visited, people to be interviewed and possible surveys to be conducted and a debriefing and reporting timetable[26].

Evaluation report format and review procedures

The draft report will be delivered to UNIDO's Independent Evaluation Division (the suggested report outline is in Annex 4) and circulated to UNIDO staff and national stakeholders associated with the project for factual validation and comments. Any comments or responses, or feedback on any errors of fact to the draft report provided by the stakeholders will be sent to UNIDO's Independent Evaluation Division for collation and onward transmission to the project evaluation team who will be advised of any necessary revisions. On the basis of this feedback, and taking into consideration the comments received, the evaluation team will prepare the final version of the terminal evaluation report.

The ET will present its preliminary findings to the local stakeholders at the end of the field visit and consider their feed-back in preparing the evaluation report. A presentation of preliminary findings will take place at UNIDO HQ after the field mission.

The TE report should be brief, to the point and easy to understand. It must explain the purpose of the evaluation, exactly what was evaluated, and the methods used. The report must highlight any methodological limitations, identify key concerns and present evidence-based findings, consequent conclusions, recommendations and lessons. The report should provide information on when the evaluation took place, the places visited, who was involved and be presented in a way that makes the information accessible and comprehensible. The report should include an executive summary that encapsulates the essence of the information contained in the report to facilitate dissemination and distillation of lessons.

[26] The evaluator will be provided with a Guide on how to prepare an evaluation inception report prepared by the UNIDO ODG/EVQ/IEV.

Findings, conclusions and recommendations should be presented in a complete, logical and balanced manner. The evaluation report shall be written in English and follow the outline given in annex 4.

VIII. Quality assurance

All UNIDO evaluations are subject to quality assessments by UNIDO Independent Evaluation Division. Quality assurance and control is exercised in different ways throughout the evaluation process (briefing of consultants on methodology and process of UNIDO Independent Evaluation Division, providing inputs regarding findings, lessons learned and recommendations from other UNIDO evaluations, review of inception report and evaluation report by UNIDO's Independent Evaluation Division).

The quality of the evaluation report will be assessed and rated against the criteria set forth in the Checklist on evaluation report quality, attached as Annex 5. The applied evaluation quality assessment criteria are used as a tool to provide structured feedback. UNIDO Independent Evaluation Division should ensure that the evaluation report is useful for UNIDO in terms of organizational learning (recommendations and lessons learned) and is compliant with UNIDO's evaluation policy and these terms of reference. The draft and final evaluation report are reviewed by UNIDO Independent Evaluation Division, which will submit the final report to the GEF Evaluation Office and circulate it within UNIDO together with a management response sheet.

Annex II – List of persons interviewed

List of Stakeholders, Partners and Investment Beneficiaries interviewed

INSTITUTION	NAME
UNIDO – Moscow ITPO office	Mr. Sergey Korotkov, Director
Altayvitaminy Pharmaceutical Company, Biysk, Altay Region	Mr. Alexander Khomutov, Chief Engineer Mr. Evgeny Batashov, Head of Research and Development Center Mr. Alexander Klemin, Head of the Workshop for the Processing of Medical Raw Materials
Moschempharmpreparaty after N.A.Semashko, Moscow	Mr. Damir Sagitov, Chief Engineer Ms. Oksana Kashina, Production Director Mr. Sergey Eremin, Head of Technical Service
Ministry of Natural Resources, Department of International Cooperation	Irina Fominykh, Deputy Head of the Department of International Cooperation Sergey Vasiliev, Advisor, Department of International Cooperation
Roszdravnadzor	Mr. Konstantin Belanov, Head of International Cooperation Division (replied that had no information about the project)
Former staff of HCFC Phase-out Project	Mr. Artem Kushnerev Mr. Vasily Tselikov Mr. Alexander Lyubeshkin

List of persons with whom the Evaluation team exchanged correspondence related with the project:

INSTITUTION	NAME
P.E.C Project Engineering Consulting AG	Mr. Christian Wolff - Managing Director
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Annex III – Documents consulted

Project Document
PIR reports - Reports to GEF 2021, 2013, 2014, 2015 and 2016 and work plan for 2017
Documentation of the contract of the national consultant hired
http://www.ozoneprogram.ru/biblioteka/publikacii/ispolzovanie_mdi/
Communication Letters between UNIDO and MNRE to prepare terminal Evaluation
Financial Report-20180418.xlsx
Regulatory documents establishing the government Commission on Technical Assistance that can grant tax exemption for import of materials and equipment for TA projects, and describing the procedure of applying for this tax exemption (in Russian)
Custom Clearance Documents
Altayvitaminy Files Shipment Purchase Order Co-financing 2016.doc Minutes of 2014_06_03 Technical Meeting ALTAIVITAMINY-PAMASOL-UNIDO Pamasol Meeting Minutes June 11 2014.pdf Working agreement between AltaiVitaminy and UNIDO Pamasol Meeting Minutes June 11 2014.docm Letter PO Altay.PDF Technical and Commercial Evaluation of the bids of technology suppliers made by Altay Commercial Evaluation Altay.doc Proforma list of equipment.xls Timetable Altay Several correspondences related with the project
Moschimpharmpreparaty Files 2017_10_24 Site Acceptance Test Purchase Order Specification of products Working agreement between Moschempharm and UNIDO Pamasol Meeting Minutes April 16 2014.pdf Pamasol Meeting Minutes April 16 2014.docm PC Submission Final Version for GF.RUS.12.001 .docx Technical and Commercial Evaluation of the bids of technology suppliers made by Moschimpharm Procurement-inventory Several correspondences related with the project