



**UNITED NATIONS DEVELOPMENT PROGRAMME  
PROJECT OF THE GOVERNMENT OF CUBA**

**PROJECT 34711**

**Title:** Phase-out of CFC consumption in the Manufacture of Aerosol Metered Dose Inhalers (MDIs) in Cuba  
**Short Title:** CUB/ARS/41/INV/23 - Phase Out of CFC in the MDI sector

**Estimated Starting Date:** 16/04/2004  
**End Date:** 30/11/2006  
**Executing Agent:** NEX - National Execution  
**National Implementing Agent:** Government of Cuba

**Summary of UNDP and Cost-Sharing Inputs in US\$ as per attached budget(s)**

INPUTS	
UNDP:	0
2G-Implementation of the Montreal Protocol	5,960,000
<b>TOTAL INPUTS</b>	<b>5,960,000</b>
<b>TOTAL</b>	<b>5,960,000</b>

**ACC Sector/Subsector:** Environment / Policies Planning and Legislation  
**DCAS Sector/Subsector:** Natural resources - Sector policy and planning  
**Primary Areas of Focus/Sub-Focus:** Promoting Environment and Natural Resources Sustainability - Promotion of sustainable natural resources management  
**Primary Type of Intervention:** Programme Support - Programme technical support  
**Primary Target Beneficiaries:** Target place (environmental habitat) - Natural features - Atmosphere

**BRIEF DESCRIPTION:**

This project will (a) phase-out the consumption of 109.1 ODP tonnes of CFC 11 and CFC 12 used in the MDIs in Cuba through the conversion of the laboratorio Julio Trigo Lopez to CFC-free technology, and (b) implement a National Transition Strategy from CFC based MDIs to CFC-free MDIs in the country. The project includes technology transfer from one established multinational enterprise that has experience in the development and manufacture of MDIs using CFC free technologies, and who has the right to transfer such technology without infringement of any intellectual property related to either the drug molecule, the method of formulation, the design of the metering valve or actuator, or the filling process.

The enterprise will provide the technology for the conversion of CFC MDI salbutamol and CFC MDI beclomethasone to HFA MDI products. The replacement products will be salbutamol and fluticasone. The technology transfer includes assistance to access relevant data in support of regulatory approval; access to dossier compilation, facility design and equipment installation; sourcing of components; clinical trial management/execution; and facility and equipment validation. Detailed specifications will be provided to ensure the equipment is adequate for its intended purpose. The technology provider will assume responsibility for all engineering and validation activities during the project implementation; will liaise directly with the production facility to ensure a seamless transition to non-CFC technology; will provide technical assistance, project management, layouts and installation qualification; and will provide assistance for the retrofitting of HFA capability for the existing CFC filling lines, once the new facility is operational.

The suppliers of the equipment will provide technical support during the building, testing and installation of the equipment; and formal (documented) training at the production site. Service contracts will be negotiated prior to placement of any order to ensure on-going technical support after procurement. Laboratorio Julio Trigo López will be responsible for all the engineering work required to adapt the production plant to suitable standard requirements of the HFA. The Government of Cuba is committed to ensure, in a period no more than six months, the preparation of a plant complying with all the specifications required (e.g., space, temperature, humidity and others) by the technology provider to produce HFA MDIs.

**IMPACT OF THE PROJECT ON THE COUNTRY OBLIGATIONS UNDER THE MONTREAL PROTOCOL:**

The Phase Out of CFC in the MDI sector is necessary to help Cuba meet the country's obligations with the Montreal Protocol, and to accomplish the phase-out calendars established in the MLF approved projects for Cuba, especially the 50% reduction target of Annex A Group I substances by 2005.

**LEGAL CONTEXT:**

This project document shall be the instrument referred to in the Standard Basic Agreement between the Government of Cuba and the UNDP, signed by the parties on 5 October 1979, and shall be governed by normal UNDP practices regarding project revisions/monitoring/evaluation, and by special procurement procedures applicable to the Montreal Protocol Programme. The project will be implemented in accordance with the agreement between the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol and UNDP signed on 21 August 1991, and the proposal approved by the Executive Committee at its Forty-First Meeting (December 2003) in Montreal, Canada.

APPROVED BY:	Signature:	Date:	Name/Title:
UNDP:		14.4.04	Bruno Moro Resident Representative UNDP-Cuba
Government:		14.4.04	Raúl Taladril Vice-Minister-MINVEC Public Authority in charge of the Coordination of International Collaboration and its execution.