National Transition Strategy to Replace CFC-based MDIs with HFA-MDIs in the Commonwealth of Independent States

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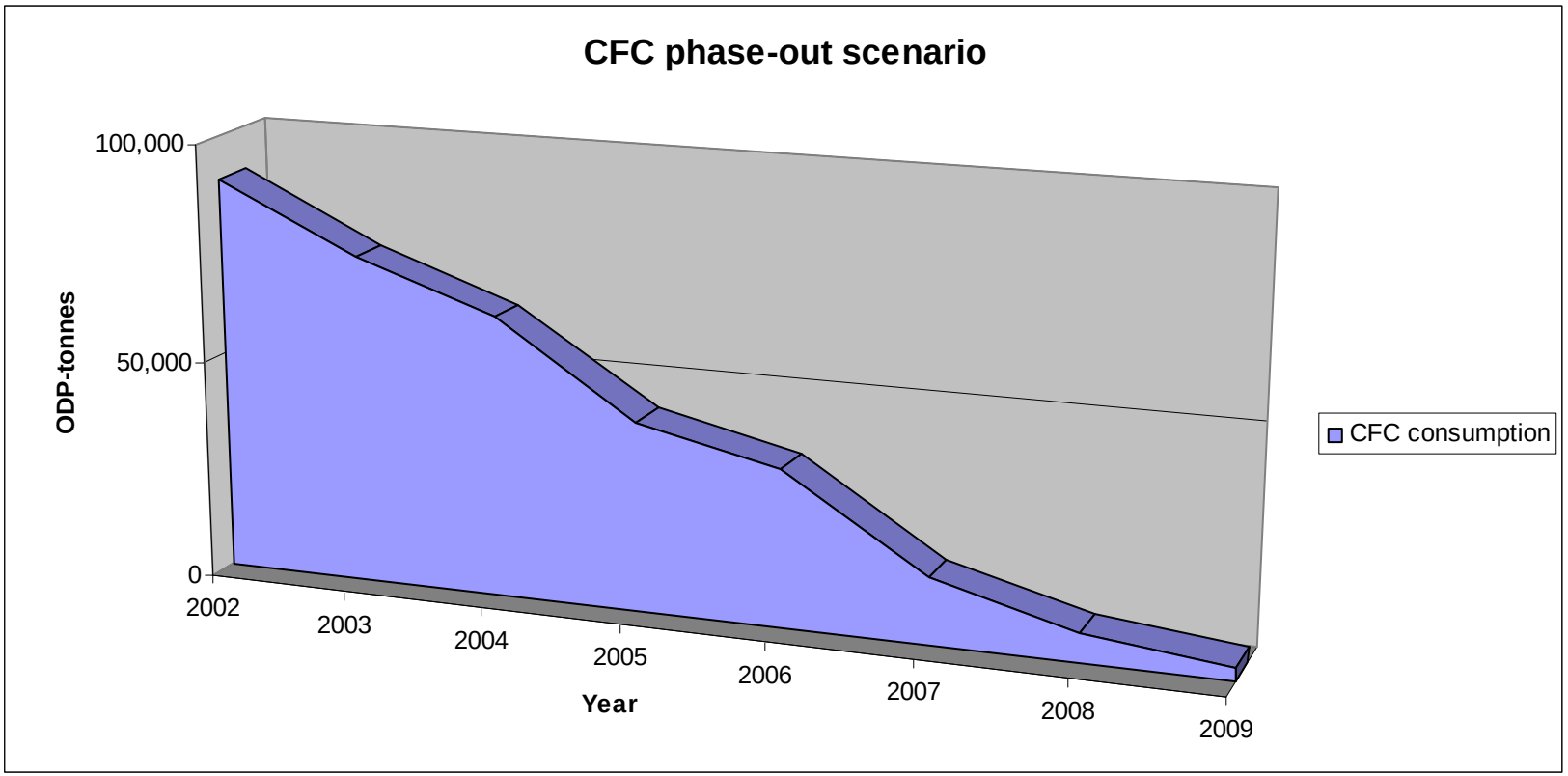
Starting point: total CFC phase-out



Essential use exemptions:

Estimated CFC usage for MDI manufacture by nominating Parties, 2010-2014

Country	2010	2011	2012	2013	2014	Total
Algeria	11	8	0	0	0	19.0
Argentina	178	107	3	0	0	288.2
Bangladesh	156.7	57	27	0	0	240.7
China	652.0	741.2	650	400	345	2,788.2
Egypt	227.4	0	0	0	0	227.4
India	344	0	0	0	0	343.6
Iran	2.2	0	0	0	0	2.2
Pakistan	35	39.6	10	0	0	84.5
Russian Federation	212	212	30	0	0	454.0
Syria	44.7	0	0	0	0	44.7
United States	92.0	-	-	-	-	92.0
Total	1,954.6	1,165.0	720.0	400.0	345.0	4,584.5

Replacement of CFCs in metered dose inhalers (MDIs)

- Purpose of MDIs
  - Treatment of asthma and chronic obstructive pulmonary disease
- Alternative technologies
  - Hydrofluorocarbons (HFCs)
  - Dry powder inhalers
  - Nebulisers and soft mist inhalers

All alternatives are “ozone friendly”, the ozone depleting potential (ODP) is zero!

Evaluation of alternative technologies

Type of inhaler	Advantages	Disadvantages
Metered dose inhalers (MDI)	-Simple actuation system -Reliable accurate dose -Compact and portable -Easy to use -Economically viable solution -Good resistance to moisture	-Dosage accuracy may be dependant on the formulation -Coordination between actuation and breathing required (except breath-actuated systems) -Complex manufacturing process
Dry Power Inhalers (DPI)	-No propellant used	-Drug release depends on the breathing capacity -Inhaled fraction is reduced if patient breathes into the system -Relatively expensive
Nebulizers	-No special breathing coordination required -Useful for new or rarely used drugs	-Not portable -Power supply necessary -Expensive -Operation takes a long time -Requires preservatives to reduce risk of bacterial contamination

Selected technology

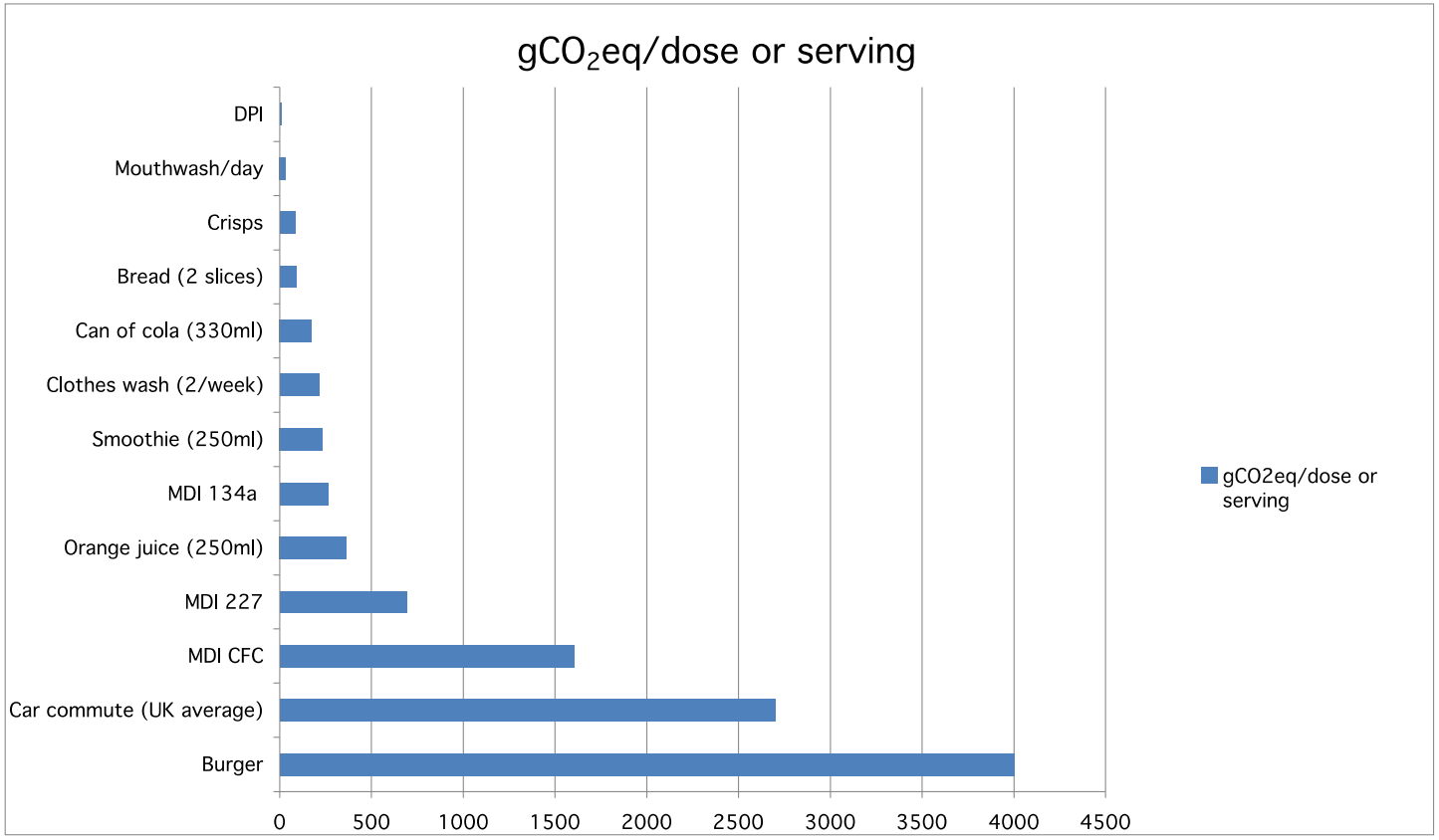
Other environmental considerations, in particular climate impact

Carbon footprints of respiratory devices and treatment methods

Respiratory devices and treatment methods	Carbon footprint Per 200 doses (Kilograms CO_2eq.)	Carbon footprint Per 2 puffs (Grams CO_2eq.)
CFC MDI	150-200	1,500-2,000
HFC-134a MDI	20-30	200-300
HFC-227 MDI	60-80	600-800
Dry Powder Inhaler	1.5-6.0	<20
Tablets	1.5-5.0	<20

Source: MTOC assessment report 2010

Estimated relative carbon dioxide emissions of everyday items compared with asthma inhalers



Source: MTOC assessment report 2010

Why is the GEF/UNIDO project important?

- Local CFC manufacture of MDIs would not be necessary to support the Russian domestic market.
- Imported non-CFC products are already approved in the Russian Federation and many competitive products are available from international companies.
- But: Support for local enterprises provides economic benefits and added value to support the patient's health.

Production of Salbutamol in 2006-2010 in the RF

Producer	**2006**	**2007**	**2008**	**2009**	**2010**
	Number of cans	Number of cans	Number of cans	Number of cans	Number of cans
Enterprise MosChimPharm Preparaty	7,817,082	6,936,000	6,643,000	7,337,000	6,500,000
Altayvitaminy	9,964,000	6,240,000	6,743,000	5,512,000	5,500,000
Total	**17,781,082**	**13,176,000**	**13,386,000**	**12,849,000**	**12,000,000**

Source: Figures were presented in the TEAP meeting in Moscow at the Ministry of Health, February, 2010

Annual demand in MDI –Salbutamol in CIS in (thousands pieces)

	Country	2005 year	2006 year	2007 year	2008 year	2009 year	2010 year
1	Azerbaijan	900	820	840	825	850	810
2	Armenia	330	340	345	320	315	310
3	Belarus	1140	1230	1280	1255	1310	1250
4	Georgia	500	550	560	550	580	520
5	Kazakhstan	1600	1650	1500	1650	1650	1550
6	Kyrgyzstan	490	470	455	480	520	580
7	Latvia	245	230	250	245	250	260
8	Lithuania	375	410	405	400	405	380
9	Moldova	320	350	370	355	380	350
10	Tajikistan	870	810	795	755	770	850
11	Turkmenistan	545	570	540	510	500	520
12	Estonia	170	155	160	160	150	165
13	Uzbekistan	2340	2550	2650	2800	2895	3100
14	Ukraine	4600	5050	5500	5600	5200	4900

General objectives of the project

- Phase-out of chlorofluorocarbons (CFCs) in the manufacture of metered dose inhalers (MDIs)
- Conversion of production facilities to CFC-free technology
- Technology transfer
- Introduction of more advanced pharmaceutical products

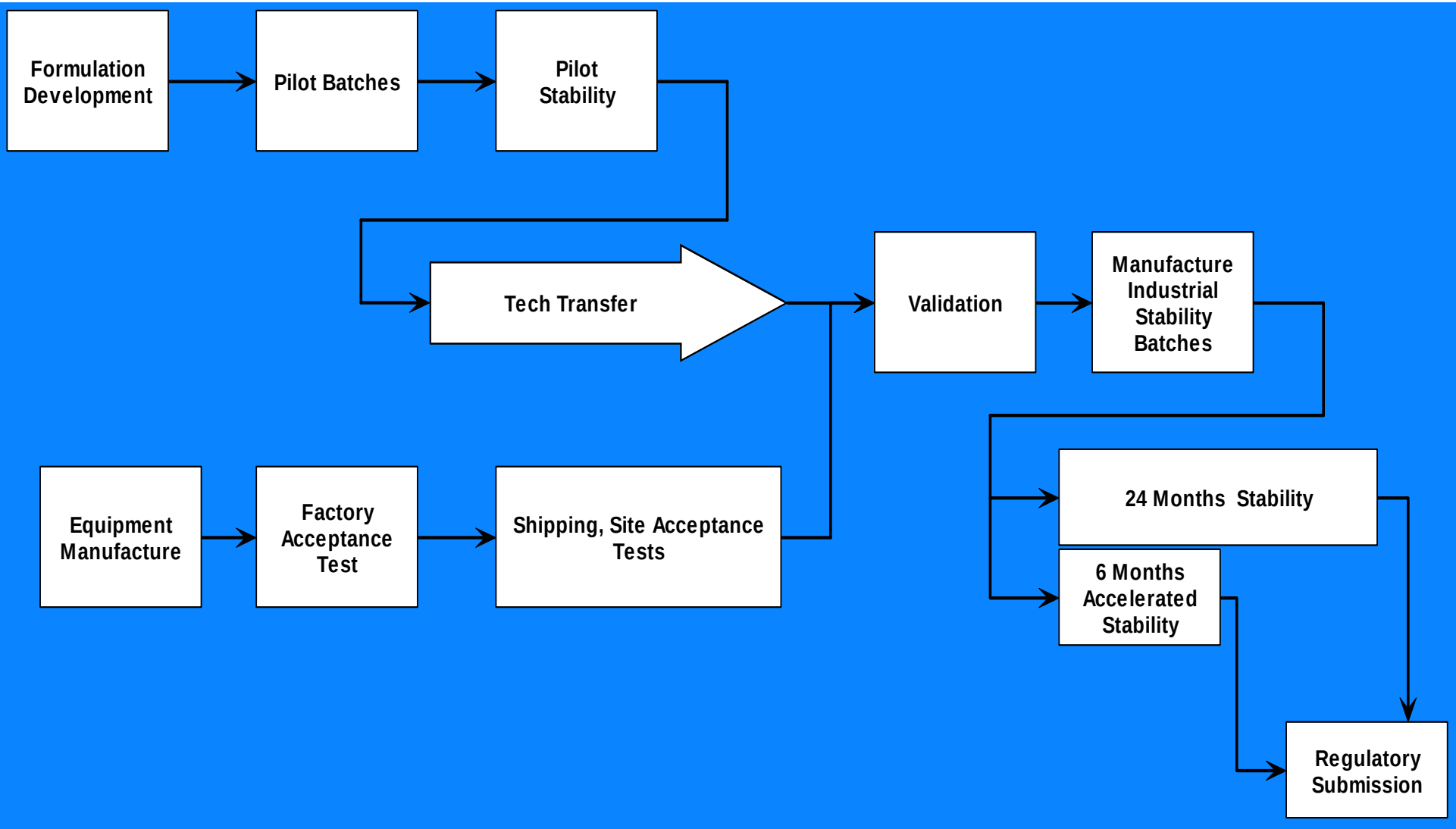
Project tasks to be solved

- The new inhaler is as safe and as effective as the previous ones;
- CFCs are damaging to the global environment but not damaging to the health of the individual;
- Although the alternative product will experience differences in appearance, dosage and taste, this do not imply any reduction in the effectiveness of the medicines.

Criteria to be met before the phase out of CFC MDIs in the RF

- Any new CFC free inhaler is at least as safe as the previous ones;
- Any new CFC free inhaler is as effective as the previous inhaler it is intended to replace;
- There should be sufficient quantities of the alternative(s) available to assure an uninterrupted supply of medication;
- Post-marketing surveillance data must confirm the safety of the alternative product(s);
- There should be sufficient types of alternative(s) available to meet the needs of different patient sub-groups.

Basic outline of the applied project strategy



Actual project budget

	Project preparation	Project	Agency fee	Total
GEF UNIDO	50,000 (50,000)	2,500,000	250,000	2,800,000
Co-financing by Russian companies		5,600,000		5,600,000
Total	100,000	8,100,000	250,000	8,350,000

Project timetable

Nº	PROJECT ACTIVITY	TIMING / RESPONSIBILITY
1	Approval of PIF by GEF Session	Nov. 2010 GEF
2	Formulation of Full Scale Project (FSP)	Feb. 2011 UNIDO
3	Approval of FSP by GEF	Nov. 2011 GEF
6	Start of project implementation (2 years)	Jan. 2012 UNIDO
7	Formulation of a new Salbutamol product	June 2011 Two companies
8	6 months stability tests of a new product	Dec. 2011 Two companies
9	Equipment procurement and installation	September 2012 UNIDO
10	Pilot production of experimental batches	October 2012 Two companies, UNIDO
11	6 months stability tests of pilot batches	March 2013 Two companies, UNIDO
12	Registration by the Ministry of Health	May 2013 Roszdravnadzor, Two companies

Thank you!