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Distr.
GENERAL

UNEP/OzL.Pro/ExCom/56/34
15 October 2008

CHINESE
ORIGINAL: ENGLISH

执行蒙特利尔议定书
多边基金执行委员会
第五十六次会议
2008 年 11 月 8 日至 12 日，多哈

项目提案：印度

本文件由基金秘书处就以下项目提案提出的评论和建议构成：

气雾剂

• 向无氟氯化碳计量吸入器过渡国家战略和药用级计量吸入器制造中淘汰氟氯化碳计划	意大利/开发计划署和环境规划署

生产

• 加快氟氯化碳生产淘汰（协定）	世界银行

项目评价表– 非多年期项目
印度

项目名称	双边/执行机构
(a) 向无氟氯化碳计量吸入器过渡国家战略和药用级计量吸入器制造中淘汰氟氯化碳	意大利/开发计划署/环境规划署
国家协调机构	环境和森林部，臭氧局

项目涉及的最新报告的消耗臭氧层物质消费数据

A: 第 7 条数据（ODP 吨，2007 年，截至 2008 年 10 月）

氟氯化碳	998.5		

B: 国家方案行业数据（ODP 吨，2007 年，截至 2008 年 9 月）

消耗臭氧层物质	计量吸入器	次级行业/数量	次级行业/数量	次级行业/数量
CFC-11	186.2			
CFC-12	421.9			
仍然有资格获得供资的剩余氟氯化碳消费量（ODP 吨）				0.0

本年度业务计划分配款		供资百万美元	淘汰 ODP 吨
	(a)	意大利 2,000,000	50
	(b)	环境规划署 400,000	0
	(c)	开发计划署 3,200,000	79.4

项目名称：	(a)
企业使用消耗臭氧层物质（ODP 吨）：	
将被淘汰的消耗臭氧层物质（ODP 吨）：	704.0
将采用的消耗臭氧层物质（ODP 吨）：	暂缺
项目期限（月）：	60
最初申请的金额（美元）：	
投资部分（美元）：	60,531,934
非投资部分（美元）：	1,170,000
总费用（美元）：	61,701,934
对应出资加调整数额（美元）：	(34,942,615)
申请的金额（美元）：	26,759,319
最终的项目费用（美元）：	
递增性资本成本（美元）：	10,164,000
产品开发费用（美元）：	10,325,000
递增性业务费用：	4,615,668
外国所有权调整额（美元）：	(3,971,386)
出口部分调整额（美元）：	(905,115)
对应方供资（美元）：	(7,531,400)
印度国家淘汰计划调整额（美元）：	(2,894,500)
过渡战略（美元）：	120,000
项目执行和监测（美元）：	280,000
申请的赠款（美元）：	10,202,267
成本有效性（美元/公斤）：	
执行机构支助费用（美元）：	851,770
多边基金项目总费用（美元）	11,054,037
对应方供资现状（是/否）：	是
包括项目监测重要事件（是/否）：	是

(*) Cadila 公司的外国所有权占 2.97%、Cipla 公司 18.42%、兰素史克公司 50.67%、 太阳药业公司 19.24%。

(**) Cipla 公司占 5.6%。

秘书处的建议	供个别审议

项目说明

1. 开发计划署作为牵头机构代表印度政府提交了向无氟氯化碳计量吸入器过渡国家战略和药用级计量吸入器制造中淘汰氟氯化碳计划（计量吸入器行业计划），供执行委员会第五十六次会议审议。提交的项目总费用为 26,759,319 美元，加上机构支助费用 2,123,543 美元。

2. 该项目将由开发计划署（24,639,400 美元加上机构支助费用 1,847,955 美元）、环境规划署（350,000 美元加上机构支助费用 45,500 美元），以及意大利政府（1,769,919 美元加上机构支助费用 230,088 美元）共同执行。

项目摘要

3. 根据计量吸入器行业计划，印度目前有五个计量吸入器制造商。其中三个制造商同时生产氟氯化碳计量吸入器和氢氟烷烃计量吸入器。

4. 在扣除因外国所有权或对应出资的调整额之前，计量吸入器行业计划的总估计费用为 61,701,934 美元，如表 1 所示。

表 1. 印度计量吸入器项目的总估计费用

说明	Cadila 公司	Cipla 公司	兰素史克公司	Midas Care 公司	太阳药业公司	共计
氟氯化碳（ODP 吨）	3.5	526.6	31.7	18.8	5.9	586.5
投资费用（美元）						
资本成本	1,218,000	11,175,600	1,178,600	780,000	780,000	15,132,200
产品开发	840,345	37,890,000	-	765,000	660,490	40,155,835
业务费用	124,842	4,411,716	330,680	308,850	67,811	5,243,899
投资费用共计	2,183,187	53,477,316	1,509,280	1,853,850	1,508,301	60,531,934
非投资费用（美元）						
技术援助						350,000
政策/监管支助						70,000
提高认识						350,000
监测/管理						400,000
非投资费用共计						1,170,000
总费用（美元）						61,701,934
总投资有效性（美元/公斤）						105.20

5. 在项目的总费用中，印度政府申请 26,759,319 美元，这是扣除了一家企业的外国所有部分、因向非第 5 条国家出口 4.9%的计量吸入器的调整额，以及企业根据第 54/5 号决定要求提供的 57%的对应缴款之后的数额。计量吸入器行业计划的增支费用的细目列于表 2。

表 2. 印度计量吸入器项目的总增量成本

说明	Cadila 公司	Cipla 公司	兰素史克公司	Midas Care 公司	太阳药业公司	共计
氟氯化碳（ODP 吨）	3.5	526.6	31.7	18.8	5.9	586.5
投资费用（美元）						
资本成本	852,600	7,208,262	223,934	546,000	546,000	9,376,796
产品开发	588,242	11,367,000	-	535,500	462,343	12,953,085
业务费用	87,389	2,845,557	62,829	216,195	47,468	3,259,438
投资费用共计	1,528,231	21,420,819	286,763	1,297,695	1,055,811	25,589,319
非投资费用（美元）						
技术援助						350,000
政策/监管支助						70,000
提高认识						350,000
监测/管理						400,000
非投资费用共计						1,170,000
总费用（美元）						26,759,319
总投资有效性（美元/公斤）						45.62

6. 本报告附件载有由开发计划署提交的计量吸入器行业计划的副本。

秘书处的评论和建议

评论

7. 秘书处审查了涉及氟氯化碳计量吸入器的项目，其依据为：

(a) 向第三十七次、第四十九次和第五十一次会议提交的关于计量吸入器次级行业的指导文件；

(b) 向第五十四次会议提交的开发计划署工作方案修正案（UNEP/OzL.Pro/ExCom/52/22 号文件第 19-31 段）；

(c) 已核准的孟加拉国、古巴、埃及、伊朗伊斯兰共和国、墨西哥和乌拉圭的计量吸入器淘汰项目；以及

(d) 执行委员会关于计量吸入器的有关决定，特别是关于核准印度计量吸入器项目编制供资问题的第 52/25(a)号决定。

8. 鉴于计量吸入器行业计划的复杂性，秘书处的评论根据以下种类进行组织：

(a) 对印度计量吸入器生产设施的分析；

(b) 豁免氟氯化碳的必要用途；

(c) 用于计量吸入器制造的氟氯化碳消费量；

(d) 产品开发；

(e) 资本成本和业务费用；

(f) 技术援助活动，包括过渡战略；

(g) 印度国家淘汰计划核准供资之后的调整额；以及

(h) 秘书处的提案。

对印度计量吸入器生产设施的分析

9. 在审查计量吸入器行业计划中所载的资料时，秘书处注意到：

(a) 2003-2007 年期间印度的计量吸入器生产总量列于表 3，如下所示：

表 3. 印度计量吸入器制造商

制造商	生产总量（百万计量吸入器）				
	2003 年	2004 年	2005 年	2006 年	2007 年
氟氯化碳计量吸入器					
Cadila Healthcare 公司	0.15	0.30	0.42	0.69	0.71
Cipla 公司	26.27	33.04	28.18	35.44	27.39
兰素史克公司	1.15	0.94	1.21	0.79	0.94
Midas-Care 公司	0.97	1.02	1.65	1.85	1.76
太阳药业公司	0.29	0.39	0.31	0.39	0.39
氟氯化碳计量吸入器小计	**28.83**	**35.69**	**31.77**	**39.16**	**31.19**
氢氟烷烃计量吸入器					
Cipla 公司	0.47	1.21	4.03	11.01	24.06
Midas-Care 公司	0.00	0.024	0.035	0.15	0.26
太阳药业公司	0.00	0.00	0.00	0.029	0.00
氢氟烷烃计量吸入器小计	**0.47**	**1.23**	**4.06**	**11.19**	**24.32**
共计	**29.30**	**36.92**	**35.84**	**50.35**	**55.51**

(b) 用于计量吸入器制造的氟氯化碳消费量从 2003 年的 578.9 ODP 吨增加到 2006 年的 763.6 ODP 吨。2007 年，氟氯化碳消费量减少至 608.1 ODP 吨，如表 4 所示：

表 4. 印度用于计量吸入器制造的氟氯化碳消费量

制造商	氟氯化碳消费量（ODP 吨）				
	2003 年	2004 年	2005 年	2006 年	2007 年
Cadila 公司	2.9	5.9	7.5	11.6	8.5
CIPLA 公司	526.6	687.6	670.9	698.2	537.7
兰素史克公司	24.6	20.1	25.9	16.9	20.1
Midas-Care 公司	18.8	21.3	29.8	29.0	34.0
太阳药业公司	6.0	7.9	6.3	7.9	7.8
共计	**578.9**	**742.8**	**740.4**	**763.6**	**608.1**

(c) 2008-2013 年期间印度用于计量吸入器的氟氯化碳和氢氟烷烃需求量预测见表 5：

表 5. 制造计量吸入器的氟氯化碳和氢氟烷烃预计消费量

推进剂	氟氯化碳和氢氟烷烃消费量（公吨）*					
	2008 年	2009 年	2010 年	2011 年	2012 年	2013 年
氟氯化碳	604	484	338	203	71	0
氢氟烷烃	566	760	983	1,205	1,405	1,556
共计	1,170	1,244	1,322	1,408	1,476	1,556

(*) 根据过去五年的增长率，并假设具备从氟氯化碳转为氢氟烷烃技术的技术和财政援助。若没有这一援助，还将需要三年才能完全淘汰氟氯化碳。

(d) 氟氯化碳计量吸入器的产量从 2003 年的 2,880 万增加到 2007 年的将近 3,120 万。然而，同期的氟氯化碳计量吸入器的国内销售量从 1,500 万台下降到了 1,000 万台。印度制造的用于国内销售和向第 5 条国家和非第 5 条国家出口的氟氯化碳计量吸入器情况见表 6：

表 6. 印度氟氯化碳计量吸入器国内销售和出口情况

参数	共计（百万计量吸入器）				
	2003 年	2004 年	2005 年	2006 年	2007 年
国内销售	14.90	15.72	16.21	18.27	10.33
向非第 5 条国家出口	0.42	0.05	0.42	0.47	1.75
向第 5 条国家出口	13.52	19.93	15.16	20.43	19.30
出口共计	13.94	19.98	15.57	20.90	20.82
生产共计	28.83	35.69	31.77	39.16	31.19
向非第 5 条国家出口(%)	1.5%	0.1%	1.3%	1.2%	5.6%

豁免氟氯化碳的必要用途

10. 执行委员会通过其第 51/34 号决定要求，*除其他外，*拥有生产氟氯化碳计量吸入器生产厂的第 5 条缔约方应获知开始考虑 2010 年淘汰日期之后的必要用途豁免需要的时间。同时，委员会在第 54/5 号决定中要求，*除其他外，*计量吸入器项目提案应明确说明“现在和过去氟氯化碳数量，以便利从氟氯化碳计量吸入器的顺利过渡和减少提出临时性必要用途豁免请求的必要性”。根据项目提案，这一过渡估计将在 2013 年 12 月之前完成，即完全淘汰氟氯化碳的强制日期四年之后。然而，在计量吸入器行业计划中没有充分考虑过渡期间氟氯化碳必要用途豁免，或储存制药级气雾剂氟氯化碳（包括数量）的必要性。在此基础之上，秘书处询问，是否与印度的主要利益攸关方就此问题进行了讨论。

11. 开发计划署指出，计量吸入器行业计划将确保在 2012 年 12 月之前完成向无氟氯化碳计量吸入器的过渡（即强制淘汰氟氯化碳 3 年之后）。计量吸入器制造商没有可用的氟氯化碳储备来满足过渡期间的需求。政府已经向利益攸关方充分介绍了必要用途的提名进程。因此，在执行机构和计量吸入器制造商的协助下，印度政府将能够在 2009 年 1 月申请必要用途。

用于计量吸入器制造的氟氯化碳消费量

12. 根据执行委员会关于战略规划的决定的基础之上，委员会商定，进一步的供资必须在国家承诺实现可持续的永久性削减消费和生产的基础之上进行预测。委员会还确认，未来几年报告的消费量可能会超出或低于商定的计算量，但是，如果消费量超过了商定的计算量，那么超出部分将不能获得供资（第 35/57 号决定）。执行委员会在第四十二次会议上核准了国家氟氯化碳淘汰计划，其中涵盖了印度所有剩余的有资格获得供资的氟氯化碳消费量（例如 847 ODP 吨）。淘汰计划基于 2003 年的氟氯化碳消费水平。在此基础之上，秘书处指出，计量吸入器项目中需要解决的氟氯化碳消费量为 586.5 ODP 吨（2003 年的氟氯化碳消费量），而不是 2007 年 704 ODP 吨的消费量。

13. 开发计划署报告，计量吸入器行业计划是在有关 2003 年的资格标准基础之上拟订的。因此，只对在 2003 年就已投入使用的生产线上生产并销售的产品进行了考虑。按照 2003 年通行的计算方法得出的增支业务费用将会很高，因为当时氟氯化碳和氢氟烷烃阀之间的费用差别更高，在氟氯化碳和氢氟烷烃推进剂之间费用也很高。因此，根据 2007 年消费水平计算得出的业务费用要低一些。

产品开发

14. 2003 年，在印度生产了含有 13 种活性成分的氟氯化碳计量吸入器，如表 7 所示。若干氟氯化碳计量吸入器制剂的浓度有所不同（例如，同样的活性成分不同的浓度）。

表 7. 按活性成分和制造工厂分列的氟氯化碳计量吸入器（2003 年）

编号	成分	企业制造的氟氯化碳计量吸入器						
		Cadila 公司	Cipla 公司	兰索史克公司	Midas-Care 公司	太阳药业公司	计量吸入器总数	计量吸入器占%
1	沙丁胺醇	30,010	16,905,000	1,044,505	611,800	56,600	18,647,915	64.6%
2	丙酸倍氯米松		4,663,000	107,475	117,900		4,888,375	16.9%
3	丙酸倍氯米松/沙丁胺醇		1,925,000		27,400		1,952,400	6.8%
4	沙美特罗/氟替卡松		778,000		10,000	163,771	951,771	3.3%
5	异丙托品	20,070	786,000		43,000		849,070	2.9%
6	布地奈德	10,010	300,000		15,200	51,738	376,948	1.3%
7	异丙托品/沙丁胺醇	20,070	293,000		61,200		374,270	1.3%
8	布地奈德/福莫特罗	69,293	191,000		75,900	27,379	363,572	1.3%
9	沙美特罗		154,000				154,000	0.5%
10	氟替卡松		134,000				134,000	0.5%
11	色甘酸钠		66,000				66,000	0.2%
12	噻托		45,000				45,000	0.2%
13	福莫特罗	1,910	31,000		11,700		44,610	0.2%
	计量吸入器共计	**151,363**	**26,271,000**	**1,151,980**	**974,100**	**299,488**	**28,847,931**	**100.0%**
	企业占总数的%	0.5%	91.1%	4.0%	3.4%	1.0%	100.0%	

15. 关于表 7 所列数据和计量吸入器项目中所列资料，秘书处注意到：

(a) 2003 年，几乎 82%的氟氯化碳计量吸入器含有沙丁胺醇（64.6%）或丙酸倍氯米松 16.9%）。另有 10%含有丙酸倍氯米松/沙丁胺醇或沙美特罗/氟替卡松的混合物；

(b) 在印度生产的所有氟氯化碳计量吸入器当中有 91%是由 Cipla 公司生产的；

(c) 第二大氟氯化碳计量吸入器生产商兰素史克公司的产量占总产量的 4%，它部分由一个非第 5 条国家的公司所有（50.67%的外国所有权）；

(d) 有几种活性成分的氟氯化碳计量吸入器至少在过去的一到两年里没有生产，即福莫特罗（Cadila 公司、Cipla 公司和 Midas Care 公司）；异丙托品（Cadila 公司和 Midas Care 公司)以及色甘酸钠(Cipla 公司)。因此，申请再次阐述这些活性成分的氢氟烷烃技术将没有资格获得供资；

开发计划署指出，上述所有的计量吸入器都于 2003 年生产。如果将 2003 年作为获得资格的参考年份，那么这些产品的开发和重新配制的其他费用都有资格获得供资。所指出的产品中有一些具体说明了其治疗记录，通常所需量较小。对这些产品的需求每年都不一样。此外，所有的计量吸入器制造企业

都确认，2003 年生产的所有氟氯化碳计量吸入器都将转为氢氟烷烃技术。

16. 与每一种活性成分的氢氟烷烃计量吸入器开发有关的总费用超过 4,000 万美元，如表 8 所示。其中，印度政府申请 12,953,085 美元（占总费用的 32.3%）。

表 8. 产品开发估计总费用（美元）

成分	Cadila 公司	Cipla 公司	兰素史克公司	Midas-Care 公司	太阳药业公司	共计（美元）	共计%
丙酸倍氯米松		4,200,000		90,000		4,290,000	10.7%
丙酸倍氯米松/沙丁胺醇		2,100,000		45,000		2,145,000	5.4%
布地奈德	109,528	4,200,000		90,000	132,098	4,531,626	11.3%
布地奈德/福莫特罗	226,610	2,100,000		90,000	132,098	2,548,708	6.4%
氟替卡松		4,200,000		90,000	132,098	4,422,098	11.0%
福莫特罗	54,764	2,100,000		45,000		2,199,764	5.5%
异丙托品	54,764	4,200,000		45,000		4,299,764	10.7%
异丙托品/沙丁胺醇	113,305	2,100,000		45,000		2,258,305	5.6%
沙丁胺醇	54,764	2,100,000		45,000	66,049	2,265,813	5.7%
沙美特罗		2,100,000				2,100,000	5.2%
沙美特罗/氟替卡松	226,610	4,200,000		90,000	132,098	4,648,708	11.6%
色甘酸钠		2,100,000		45,000		2,145,000	5.4%
噻托		2,100,000		45,000	66,049	2,211,049	5.5%
费用共计（美元）	840,345	37,800,000	-	765,000	660,490	40,065,835	100.0%
申请的费用共计（美元）	588,242	11,367,000	-	535,500	462,343	12,953,085	

17. 在审查产品开发的总费用时，秘书处注意到：

(a) 尽管 2003 年只生产了 13 种不同的活性成分氟氯化碳计量吸入器，但是，计量吸入器行业计划建议重新配制 55 种不同的氟氯化碳计量吸入器，其中包括一些两种不同浓度被列为两种不同产品的活性成分；

开发计划署指出，含有同样活性成分的计量吸入器对每一种浓度仍然包括一些产品的开发阶段，诸如开发和稳定性研究，以便对产品进行登记。如果有三种或三种以上的浓度，惯例是开发出最高浓度和最低浓度，并进行正式的稳定性评估，而对中等浓度的产品则只进行桥接试验（对此已给予了适当的考虑）。

(b) 兰素史克公司没有为氢氟烷烃计量吸入器的开发申请任何的供资（即该费用将由公司承担）。然而，新配方的计量吸入器由于需要更昂贵的滤毒罐和阀，其业务费用更为高昂；

(c) 产品开发费用中包括一些在 2003 年以后开始生产的氟氯化碳计量吸入器，即沙美特罗/氟替卡松、(Cadila 公司)、噻托/福莫特罗和主旋沙丁胺醇(Cipla 公司)以及氟替卡松和噻托(太阳药业公司)。因此，与这些活性成分转向氢氟烷

烃技术相关的费用没有资格获得供资；

开发计划署称，计量吸入器于 2004 年进入商业供应链，2003 年已经开始商业大规模的批量生产，并提交了登记申请。在此基础之上，这些计量吸入器被纳入了计量吸入器行业计划。

(d) 每一种活性成分的产品开发费用在制造企业当中各有不同。然而，对每一种产品的开发所申请的是同样的经费水平，不管计量吸入器的年产量为多少（比如，Cipla 公司申请 210 万美元用于开发总产量为 1,690 万台的沙丁胺醇计量吸入器，另外申请 210 万美元用于开发年总产量只有为 45,000 台的噻托计量吸入器）。此外，对于不同浓度的氟氯化碳计量吸入器，至少在为两中浓度的计量吸入器申请供资（主要是最低和最高的浓度）；

(e) 为解决这些问题，开发计划署指出，产品开发的费用是一个国家/企业具体情况的一项职能，取决于可利用的基准技术能力和内部制度/间接费用。此外，对海外市场的监管需求会增加开发费用。在印度计量吸入器制造企业的中，特别是占据巨大海外市场的 Cipla 公司，这一点可以对开发费用产生重大的影响。开发费用体现的是固定的支出，不管制造的产量有多少，也需要确保产品精心开发，进行适当的登记，并且是安全而有效的。在用两种不同的活性成分对计量吸入器进行重新制剂时，必须对两种浓度采用两种分析方法；成分筛查以确定是否与每一种浓度相融，还必须使两种浓度的进行相互作用；在稳定阶段对所有时间点需要开展的分析次数加倍。

资本成本和业务费用以及技术援助活动

18. 应要求获得更多关于印度计量吸入器制造厂中外国所有权部分的信息的请求，开发计划署报告如下：Cadila 公司为 2.97%的外国所有权、Cipla 公司为 18.42%的外国所有权、兰素史克公司为 50.67%的外国所有权，太阳药业公司的外国所有权为 19.24%。

19. 对于 2003 年之前建立的每一条计量吸入器的生产线，秘书处和开发计划署就其装机容量、技术更新、参照基准设备的设备项目资格以及设备的费用。业务费用按照 2007 年的生产水平进行计算，而非 2003 年的水平。

20. 计量吸入器行业计划包括申请 1,170,000 美元，用于以下非投资部分的活动：

(a) 正在为执行向无氟氯化碳计量吸入器过渡的国家战略提供技术援助（350,000 美元），用于，*除其他外*，编制待采购设备的说明、评价供应商的报价、在获益企业初创期间为其提供新设备和进程方面的指导、协助评价生产和产品质量试验、项目试运转，包括视情况销毁使用氟氯化碳的设备、氟氯化碳库存耗减的核查，以及对无氟氯化碳生产进程的核查；项目完成交割以及报告要求；

(b) 政策和条例支助（70,000 美元），其中包括氟氯化碳计量吸入器供应的控制和无氟氯化碳替代物的推广；

(c) 提高认识和能力建设（350,000 美元），其中包括信息散发和提高认识活动、编制和分发宣传资料和提高公众认识；以及

(d) 管理和监测股（400,000 美元），将负责协调战略各个部分的执行、进度报告、协调企业一级的执行和淘汰活动，以及核查与认证企业一级的氟氯化碳淘汰。

21. 关于非投资活动，秘书处注意到：

(a) 印度的哮喘患者和采用计量吸入器治疗的人口很少，并在过去的几年中持续下降；

(b) 氢氟烷烃计量吸入器在该国占据了主要的市场份额。2007 年，氢氟烷烃计量吸入器约占印度计量吸入器生产总量的 44%。预计氢氟烷烃计量吸入器的生产还将继续增加，以替代氟氯化碳计量吸入器。此外，干粉吸入器目前由 Cipla 公司和太阳药业公司生产；

开发计划署表示，氢氟烷烃计量吸入器技术在市场占有率方面的主要障碍在于费用的增加、药物和设备销售价格的法定管制、关于氢氟烷烃计量吸入器信息和经验的广泛宣传不足，即使在保健提供者当中也是如此，以及必须加强有关政策/条例。由于这些障碍，计量吸入器制造商在国内销售方面无法获得充分的补偿，因此，出口成为更好的选择。这些障碍只能通过《蒙特利尔议定书》机制，运用可用的技术和财政干预加以克服。在本地生产干粉吸入器单一剂量产品的理由是满足那些适用计量吸入器方面有困难的老年患者这一特定群体的需求，但并不是为了替代氟氯化碳计量吸入器用于哮喘和慢性肺部疾病的治疗。然而，印度的患者和医生对干粉吸入器单一剂量产品并不是十分欢迎。

(c) 尽管印度有若干家计量吸入器的制造企业，但是，总产量中有 91%以上都由一家企业生产；有几条生产线已经转为技术，另外，有三家企业已经在生产氢氟烷烃计量吸入器；

开发计划署表示，尽管有一家计量吸入器的制造企业是印度最大的，但是，过渡战略很复杂，涉及到很多利益攸关方，并考虑到了敏感的社会和卫生影响。不能将其视作简单的淘汰项目，因为这样就低估了其中所含的挑战。

<u>印度国家淘汰计划核准供资之后的调整额</u>

22. 考虑到剩余有资格获得供资的消费量已包括了用于生产计量吸入器的氟氯化碳，计量吸入器行业计划的总供资水平应扣除 2,894,500 美元，以避免重复计算。为了计算这一调

整额，秘书处注意到：

(a) 第四十二次会议根据 2003 年的氟氯化碳消费量核准了印度的淘汰计划；

(b) 根据淘汰计划，只有 120 ODP 吨氟氯化碳用于生产氟氯化碳计量吸入器。淘汰计划中报告的氟氯化碳消费量大大低于印度政府提交给第五十二次会议的关于编制印度计量吸入器淘汰项目提案中所报告的 639.2 ODP 吨氟氯化碳消费量，也低于提交给第五十六次会议的项目提案中所报告的 578.9 ODP 吨氟氯化碳消费量；

(c) 印度淘汰计划费用（以及大多数非低消费量国家的国家淘汰计划）的计算采用制冷剂服务行业的 5.00 美元/公斤这一成本有效值，加上适用于每一个仍然使用氟氯化碳的制造行业的成本有效限额，以及监测和报告的额外供资。

23. 考虑到上述因素，计量吸入器行业计划的调整额应当在 2003 年 578.9 ODP 吨的氟氯化碳消费量（这是计量吸入器行业最精确的消费量）基础之上，并采用 5.00 美元/公斤这一成本有效值进行计算。

秘书处的提案

24. 根据秘书处在审查开发计划署提交的计量吸入器行业计划中提出的问题和评论、大量具有不同活性成分和浓度的计量吸入器、在项目审查期间所收集的额外信息，以及多边基金在计量吸入器行业所积累的经验，秘书处向开发计划署建议下文所述的替代方法，用于确定计量吸入器行业计划的增支成本。这一方法与多边基金目前的政策和指导方针是一致的，并成功地解决了秘书处在项目审查进程中提出的所有成本问题。

过渡战略

25. 计量吸入器行业计划查明了若干可以在计量吸入器行业使氟氯化碳转为无氟氯化碳替代物的关键要素。这些要素包括支助对消耗臭氧层物质政策和条例的审查，其中包括考虑为采纳无氟氯化碳替代物提供财政激励和无氟氯化碳计量吸入器核准快速程序；考虑申请 2010 年淘汰日期之后的必要用途豁免，以及公共认识和信息散发。考虑到制造厂数目众多，地域分配和计量吸入器活性成分中很多将转为氢氟烷烃技术，过渡战略的费用将为 120,000 美元。

产品开发

26. 计算开发氢氟烷烃计量吸入器费用的提案基于以下考虑：

(a) 2003 年，印度生产了 13 种计量吸入器活性成分。其中 6 种以一种以上的浓度生产。开发计划署已收到确认，称这些氟氯化碳计量吸入器将被转为氢氟烷烃技术；

(b) 生产的计量吸入器中大约有 95%含有以下活性成分：沙丁胺醇、丙酸倍氯米松、丙酸倍氯米松/沙丁胺醇、沙美特罗/氟替卡松和异丙托品（见上文表 7）。拟议 750,000 美元用于每一种活性成分的氢氟烷烃计量吸入器开发（这一供资水平略低于一些已核准的计量吸入器项目）。如果生产同样活性成分的计量吸入器的企业不止一家，则为那些额外的生产企业拟议提供 100,000 美元，用于支付*现场*测试、编制档案和登记相关的费用。例如，开发沙丁胺醇计量吸入器所需的总费用将为 1,050,000 美元，由四家企业生产；

(c) 为配制五种活性最强的成分的其他浓度拟议了 375,000 美元。如果有一家以上的企业生产同一种活性成分，那么将为每一家额外的生产企业拟议 100,000 美元，用于支付与编制档案和登记和卫生当局核准相关的费用；

(d) 正在为剩余的八种活性成分拟议同样的办法（即异丙托品、布地奈德、异丙托品/沙丁胺醇、布地奈德/福莫特罗、沙美特罗、氟替卡松、色甘酸钠、噻托、福莫特罗），其供资水平如下：

(一) 300,000 美元用于上述活性成分的开发。如果有一家以上的企业生产同一种活性成分，那么将为每一家额外的生产企业拟议 100,000 美元，用于支付与编制档案和登记和核准相关的费用；以及

(二) 正在拟议 150,000 美元用于配置上述活性成分的其他浓度。如果有一家以上的企业生产同一种活性成分，那么将为每一家额外的生产企业拟议 100,000 美元，用于支付与编制档案和登记和核准相关的费用；

(e) 兰素史克公司生产的丙酸倍氯米松开发费用将由该企业负担。

27. 与氢氟烷烃技术开发有关的总费用为 10,325,000 美元（在考虑任何根据有关决定的调整额之前。

<u>资本成本和业务费用</u>

28. 五家计量吸入器制造厂生产线转用的供资水平如下；

(a) 在新的两阶段生产线配额的基础上为每一家产量规模中等（即 20 和 32 罐/分钟）的四家制造厂提供 726,000 美元用；

(b) 为 2003 年氟氯化碳消费量超过 520 ODP 吨的唯一一家制造厂提供 7,260,000 美元其计算的标准是 5 条单独生产线单一价格 1,452,000 美元。

29. 因此，与转换为氢氟烷烃技术相关的总资本费用达 10,164,000 美元，其中包括安装、调试和应急费用。

30. 业务费用根据 2003 年生产的计量吸入器的总数目（即，大约 2,880 万台）以及 0.16 美元/计量吸入器的单一价格，这一单一价格是与印度记录的氢氟烷烃新阀相关的增支费用，加上每一额外混合物增加 0.01 美元的标准计算。计算得出的业务费用达 4,615,668 美元。

31. 考虑到五家制造企业若干条制造生产线所生产的计量吸入器活性成分的种类数目，秘书处建议成立一个项目执行和监测股，总费用为 280,000 美元，主要负责，除其他外，协助编制待采购设备的说明、评价供应商的报价、在获益企业初创期间为其提供新设备和进程方面的指导、解决在执行战略各个部分中采用新的协调方面的技术问题，以及监测与核查。

供资摘要

32. 完全淘汰印度计量吸入器制造中使用的氟氯化碳拟议的供资水平如下：

说明	**美元**
产品开发	10,325,000
资本成本	10,164,000
业务费用	4,615,668
项目费用小计	25,104,668

33. 从 25,104,668 美元的这一数字看，下列数额必须被扣除：

说明	**美元**
外国所有权	(3,971,386)
向非第 5 条国家出口	(905,115)
对应出资 (30%)	(7,531,400)
印度国家淘汰计划调整额	(2,894,500)
调整额小计	(15,302,401)

34. 因此，印度的计量吸入器行业计划的总费用如下：

项目费用	9,802,267 美元
过渡战略	120,000 美元
项目执行和监测股	280,000 美元
总计	10,202,267 美元

35. 秘书处拟议的供资水平已与双边和执行机构商定。机构间的供资分配如下：

供资（美元）	**意大利**	**开发计划署**	**环境规划署**	**共计**
项目费用	2,000,000	8,082,267	120,000	10,202,267
机构支助费用	230,000	606,170	15,600	851,770
总费用	2,230,000	8,688,437	135,600	11,054,037

36. 印度政府可以酌情灵活地将计量吸入器行业计划下可利用的资金用于实现完全淘汰计量吸入器行业的氟氯化碳的活动，同时遵循多边基金的有关决定和准则。

建议

37. 注意到来自计量吸入器制造企业的大量对应捐助、使计量吸入器行业完成到无氟氯化碳替代物的完全转化的必要性，并鉴于秘书处的评论，谨建议执行秘书处考虑核准向无氟氯化碳计量吸入器过渡的国家战略以及在印度药用级计量吸入器制造中淘汰氟氯化碳的计划所需的 10,202,267 美元加上机构支助费用 851,700 美元，具体分配如下：

(a) 意大利政府为 2,000,000 美元加上机构支助费用 230,000 美元；

(b) 开发计划署为 8,082,267 美元加上机构支助费用 606,170 美元；以及

(c) 环境规划署 120,000 美元加上机构支助费用 15,600 美元。

加速淘汰氟氯化碳生产（协定）

导言

38. 世界银行代表印度政府向执行委员会第五十六次会议提出本报告附件一所载印度和多边基金执行委员会关于加速淘汰氟氯化碳生产的协定订正草案。为便利阅读案文，原决议草案改动之处以黑体标出。

背景

39. 2008 年 4 月，执行委员会在第五十四次会议上决定：

> “(a) 原则上核准为在 2008 年 8 月 1 日之前、即早于现有淘汰时间表 17 个月关闭印度的氟氯化碳生产供资 317 万美元，但有一项谅解，即：2008 年 1 月 1 日至 7 月 31 日之间主要用于计量吸入器用途的额外氟氯化碳生产将不会超过 690 公吨；
>
> (b) 请基金秘书处和世界银行编制并向执行委员会第五十五次会议提交关于加快氟氯化碳生产关闭项目的协定草案。协定草案应包括政府所作的承诺，即政府将确保：除了为满足计量吸入器行业的需求而可能需要的不超过 135 公吨的数量外，2007 年底剩余的氟氯化碳储存（1,363 公吨）将不晚于 2009 年 12 月 31 日之前出口；
>
> (c) 请印度在其协定草案中确认 2008 年和 2009 年其国内氟氯化碳的需求，以便确定将要出口的氟氯化碳的准确数量；
>
> (d) 协定草案应说明并应包括完成必要的拆除活动的必要步骤以及确认确已落实生产关闭和拆除的核查。
>
> （第 54/37 号决定）”

40. 执行委员会在同次会议还决定协助印度遵守淘汰氟氯化碳消费量的协定所规定的淘汰目标，这与国家淘汰氟氯化碳的生产量和消费量的综合管理有关，情况如下：

> “(g) 关于氟氯化碳消费行业协定，
>
> (一) 印度生产不超过 690 公吨的各类氟氯化碳，主要是用于在 2008 年 8 月 1 日之前制造计量吸入器；

(二) 印度氟氯化碳生产商2008年和2009年销售不超过825公吨用于计量吸入器生产的氟氯化碳，其中包括690公吨用于新的生产，自现有储存中再加工135公吨；

(三) 印度出口1,228公吨各类氟氯化碳不得晚于2009年12月31日；

(四) 印度不再进口任何氟氯化碳。

（第54/35号决定）”

41. 世界银行向执行委员会第五十五次会议提交了协定草案，以便对加速淘汰氟氯化碳生产作出决定。不过，印度又在会中撤销提案，因为需要进一步澄清草案中关于处罚条款的适用范围。

秘书处的评论和建议

评论

42. 协定订正草案包括了上述决定的所有条款。订正草案第7段内的处罚条款明确表明包括第2段和第5段内提到的承诺。拟议付款的条件取决于世界银行进行的核查结果，并且把两次付款安排在2009年和2010年的首次会议也符合情理，因为届时世界银行将提出附有核查报告的年度工作方案。

建议

43. 秘书处建议执行委员会核准协定订正草案。

附件一

印度和多边基金执行委员会关于加速淘汰氟氯化碳生产的协定

1. 本协定是对执行委员会和印度在第二十九次会议上缔结的《印度化工生产部门协商一致协定》（“《现行协定》”）的补充。本协定代表了印度（“国家”）和执行委员会就于2008年8月1日前加速淘汰氟氯化碳化工生产达成的谅解。

2. 国家同意修订其淘汰氟氯化碳生产的时间表，条件是：

(a) 印度生产不超过 690 公吨的各类氟氯化碳，主要是用于在 2008 年 8 月 1 日之前制造计量吸入器；

(b) 印度氟氯化碳生产商 2008 年和 2009 年销售不超过 825 公吨用于计量吸入器生产的氟氯化碳，其中包括 690 公吨用于新的生产，自现有储存中再加工 135 公吨；

(c) 印度出口 1,228 公吨各类氟氯化碳不得晚于 2009 年 12 月 31 日；

(d) 印度不再进口任何新产的氟氯化碳；

(e) 源自（a）项下生产活动的任何副产品、非药品类氟氯化碳都会被计入附录 1 表 1 第 2 行中的限额，并可被释放到市场上；

(f) 本协定不包含缔约各方为满足印度的必要用途而商定的任何氟氯化碳生产；以及

(g) 除上述各项外，现行协定中的其他条件也适用于本协定。

3. 国家承认，在接受本协定和执行委员会履行附录1表2所述供资义务的情况下，它将失去就淘汰氟氯化碳生产申请或接受多边基金的进一步供资的资格。

4. 以国家遵守本协定规定的义务为条件，执行委员会原则上同意向国家提供附录1（供资）表2第3行所列资金。执行委员会将在执行委员会第五十七次和第六十次执行委员会会议上提供与新的加速淘汰有关的供资付款。关于《现行协定》规定的2009年的随后一期付款，其发放将依照《现行协定》中规定的条款和条件执行。

5. 国家将遵守附录1表1第2行所示生产限额。国家还同意接受执行机构（世界银行）的独立技术审计，以便根据本协定，确认氟氯化碳的产量、再加工限额、销售量（出口销售和国内销售）及库存。

6. 国家同意对管理和执行本协定和为履行本协定项下义务由国家或代表国家所开展的全部活动全面负责。国家还同意制定政策或建立执行机制，以确保通过执行附录2所列政策和管制措施，协调生产和消费行业开展的氟氯化碳淘汰工作。

7. 如果国家出于任何原因没有达到消除各种物质的目标，或没有遵守本协定，则国家同意该国将无权得到资金。执行委员会将酌情处理，在国家证明已履行接受资金拨付时间表所列下一期资金之前应当履行的所有义务之后，将按照执行委员会确定的订正资金拨付时间表恢复供资。另外，印度了解执行委员会可以针对未能实现***本协定第2段和第5段中承诺的***削减量，依据每ODP吨1,000美元的标准，减少随后各期付款的资金。

8. 不得以执行委员会今后做出的、可能对国家任何其他生产行业项目或任何其他相关活动的供资产生影响的决定为基础，修改本协定的供资成分。

9. ***国家、执行委员会和世界银行可相互同意采取步骤，促进本协定的执行***。国家尤其应当为世界银行获得核查本协定遵守情况所必需的信息提供便利。

10. 本协定所列所有协定仅在《蒙特利尔议定书》范围内按照本协定的规定执行。除本协定另有规定外，本协定适用的所有术语均具有《议定书》赋予的含义。

附录 1 指标和供资

表 1. 生产指标

说明	年份		
	2008	**2009**	**2010**
1. 《现行协定》规定的指标（ODP 吨）	2,259	1,130	0
2. 本协定规定的生产量（ODP 吨）	690	0	0

表 2. 供资

说明	年份		
	2008	**2009**	**2010**
1. 现行协定规定的供资额（千美元）	6,000	6,000	0
2. 现行协定规定的支助费用（千美元）	450	450	0
3. 本协定的总调整供资额（千美元）	-	2,113	1,057
4. 本协定调整供资的支助费用（千美元）	-	0	238
5. 发放给国家和执行机构的资金总额	6,450	8,563	1,295

附录 2　政策和管制措施

1. 依照国家在执行委员会第五十四次会议上提交的《行动计划》，国家同意采取下列措施：

(a) 于 2008 年 8 月 1 日之前禁止生产各类氟氯化碳，各缔约方今后可能商定的为必要用途开展的生产除外；

(b) 确保臭氧规则的消费时间表与侧重制冷维修行业的、印度和执行委员会关于印度国家氟氯化碳消费量淘汰的协定之附录 2-A 第 3 行中的消费限额保持一致；

(c) 印度将不再进口新的/原产氟氯化碳；以及

(d) 加强氟氯化碳库存量和进口量调度情况监测制度，如果有的话。

- - -

MULTILATERAL FUND FOR THE IMPLEMENTATION OF THE MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER

PROJECT COVER SHEET

COUNTRY:	INDIA		**IMPLEMENTING AGENCY:**	UNDP
			COOPERATING AGENCY:	UNEP
			BILATERAL AGENCY:	Italy
PROJECT TITLE:	National Strategy for Transition to non-CFC MDIs and Plan for phase-out of CFCs in the manufacture of pharmaceutical Metered Dose Inhalers (MDIs) in India			
PROJECT IN CURRENT BUSINESS PLAN:			Yes	
SECTOR:			Aerosols	
SUB-SECTOR:			Pharmaceutical MDIs	
ODS USE IN SECTOR:	Baseline (Average of 2003 & 2004):		693.97	ODP tonnes
ODS USE IN SUB-SECTOR:	(Average of last 3 years):		704.03	ODP tonnes
PROJECT IMPACT:			704.03	ODP tonnes
PROJECT DURATION:			60	months
PROJECT COSTS:	**Investment Components**			
	Incremental Capital Costs:	US$	13,756,545	(UNDP)
	Contingencies (10%):	US$	1,375,655	(UNDP)
	Product Development Cost	US$	40,155,835	(UNDP)
	Incremental Operating Costs:	US$	5,243,899	(UNDP)
	Sub-total:	***US$***	***60,531,934***	
	Non-Investment Components			
	Technical Assistance:	US$	350,000	(UNDP)
	Policy/regulatory Support:	US$	70,000	(UNDP)
	Awareness Actions:	US$	350,000	(UNEP)
	Monitoring and Management:	US$	400,000	(UNDP)
	Sub-total:	***US$***	***1,170,000***	
	Total Costs:	**US$**	**61,701,934**	
LOCAL OWNERSHIP (Net overall):			98.4%	(Funding request adjusted)
EXPORT COMPONENT (To non-Article-5 countries):			4.9%	(Funding request adjusted)
ESTIMATED COUNTERPART FUNDING:		US$	34,942,615	(@57% from recipients)
REQUESTED GRANT:		US$	**26,759,319**	
COST EFFECTIVENESS:		US$/kg/y	38.00	
AGENCY SUPPORT COSTS:		US$	1,847,955	(UNDP)
		US$	45,500	(UNEP)
		US$	230,088	(Italy, executed by UNDP)
TOTAL COST TO MULTILATERAL FUND:		**US$**	**28,882,862**	
STATUS OF COUNTERPART FUNDING:			Letters from beneficiary enterprises obtained	
PROJECT MONITORING MILESTONES:			Included	
NATIONAL COORDINATING BODY:			Ozone Cell, Ministry of Environment & Forests	

PROJECT SUMMARY

This project articulates India's national strategy for transition to non-CFC MDIs and will result in the elimination of CFC consumption in the manufacture of pharmaceutical Metered Dose Inhalers (MDIs) in India by 2012. The project involves development of suitable alternative products including HFA-based metered dose inhalers at five enterprises who currently manufacture CFC-based MDIs in this sub-sector. Under this project, the enterprises will develop alternative formulations and implement conversions for several of their CFC-based MDI products. The substantial counterpart funding envisaged from the enterprises supplementing the requested funding, will cover formulation development and conversion of remaining products and result in complete conversion of all CFC-based MDIs in India to non-CFC alternatives.

This project is presented as an aggregate of technology conversion costs covering incremental capital and operating costs, technical assistance costs and contingencies, covering equipment and technology for manufacturing HFA-based MDIs, product development and technology transfer, project supervision and implementation and also eligible costs for provision of policy/regulatory support, institutional and technical assistance, awareness actions and monitoring & management

IMPACT OF THE PROJECT ON THE COUNTRY'S MONTREAL PROTOCOL OBLIGATIONS

The approval of this project will help India in meeting its Montreal Protocol obligations, such as phased reductions in ODS consumption as per the agreed schedules and eliminate the use of ODS in the pharmaceutical MDI sector in India by 2012.

Prepared By: UNDP with inputs from UNEP **Reviewed By:** Under review **Version:** 02 August 2008

56th Meeting of the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol

NATIONAL STRATEGY FOR TRANSITION TO NON-CFC MDIS AND PLAN FOR PHASE-OUT OF CFCS IN THE MANUFACTURE OF PHARMACEUTICAL METERED DOSE INHALERS (MDIS) IN INDIA

Prepared By

OZONE CELL, MINISTRY OF ENVIRONMENT AND FORESTS
GOVERNMENT OF INDIA

IN BILATERAL COOPERATION WITH
GOVERNMENT OF ITALY

With the assistance of

UNITED NATIONS DEVELOPMENT PROGRAMME (UNDP)
Lead Implementing Agency

UNITED NATIONS ENVIRONMENT PROGRAMME (UNEP)
Cooperating Agency

EXECUTIVE SUMMARY

The conversion of the majority of CFC consuming sectors in Article 5 countries under the Montreal Protocol has been completed or is in an advanced stage of implementation, however, to date only few projects to convert the production of CFC-based pharmaceutical Metered Dose Inhalers have been funded by the Multilateral Fund. The Montreal Protocol control schedule requires a complete phase out of CFCs by 2010; however, if the CFC consumption in manufacturing of MDIs is not addressed fully, it may present a significant risk of non-compliance in Article-5 MDI manufacturing countries. Since the manufacture of these drugs is essential for ensuring effective therapeutic treatment to asthma and COPD patients in these countries, there is a justifiable need for CFCs in this sector until the manufacturing can be adapted to use alternative technologies. Decisions 49/33, 50/19 and 50/20 of the Executive Committee of the Multilateral Fund, recognized this risk in countries manufacturing MDIs including India, and urged for the preparation of conversion projects in this sector, to address this issue as soon as possible.

In response to Decisions 50/19 and 50/20, India, with assistance from UNDP, has prepared a National Strategy for Transition to non-CFC MDIs that provides an overall framework to address, in a coordinated way, the sustainable phase-out of CFC use in the manufacture of MDIs in India, ensuring that its obligations under the Montreal Protocol are complied with, potential economic losses to the indigenous MDI manufacturing industry are minimized and most importantly, asthma and COPD patients are not deprived of essential and cost-effective inhaled therapy. The plan for phase-out of CFC-based pharmaceutical MDIs in India is an integral component of the National Strategy for Transition to non-CFC MDIs and prepared with assistance from UNDP as Lead Agency, UNEP as Cooperating Agency and Government of Italy as the Bilateral Cooperating Agency (with a contribution of US$ 2 million). The provisions of Executive Committee Decisions 51/34 and 54/5 have been duly considered in the preparation of this proposal.

The primary objective of this project is to sustainably phase out the consumption of CFCs used in the manufacture of pharmaceutical Metered Dose Inhalers (MDIs) in India by 2012. This involves the development of suitable alternative products, including HFA-based MDI formulations and the conversion to HFA-based MDI manufacturing technology at five eligible enterprises in India. There are over twenty MDI formulations produced in India and over forty products/strengths commercialized. This project will result in the conversion or replacement of all the current CFC-based formulations/products, taking into account the specific characteristics, status of progress in the formulation process and registered eligible products of each one of the enterprises involved. The enterprises will take responsibility of addressing the conversion of non-eligible formulations through their own resources and through the capacity built in this project. In order to achieve these conversions, each enterprise will require the development of a number of new MDI formulations and installation of suitable manufacturing equipment to allow them to produce HFA-based MDIs.

The cost of the proposed strategy and plan is presented as an aggregate of industrial conversions encompassing product development, technical assistance, incremental capital costs and incremental operating costs involved in conversion to HFA-based formulations and also support for awareness, policy and regulations, institutional and technical support and monitoring & management. All eligible drugs will be converted, keeping in mind their relevance to and specific needs of patients and ease of conversion. The funding requested covers cost of production equipment and installation, product development and transfer to the enterprises including stability testing and laboratory analysis, along with overall project supervision and implementation. The beneficiary enterprises will finance the cost of product registration and overheads.

Although the transition process from CFC-based MDIs to HFA-based MDIs in India is now partially underway, it involves an interim period during which production of both CFC-based MDIs and HFA-based MDIs need to occur simultaneously to ensure continuity in availability of proven products in the market in the interests of asthma and COPD patients. This therefore means that HFA-based MDI manufacturing equipment needs to be installed and operationalized prior to shutting down CFC-based MDI manufacturing lines.

Given the CFC consumption limits established for India currently and for the future, it is imperative to accelerate phase-out of CFCs in pharmaceutical MDIs, while ensuring availability of non-CFC MDIs as soon as possible. Considering the current situation of production of pharmaceutical grade CFCs at the global level, it is necessary to make provisions for making pharmaceutical grade CFCs available to meet the requirement of MDIs during the transition period. In this regard, the enterprises in collaboration with the Government, will determine the amount of pharmaceutical grade CFCs that would be required ensure availability of proven drugs to patients, while the HFA-based MDIs are being developed, tested and registered, leading to full-fledged commercial production.

The funding of this project by MLF to cover the eligible incremental costs is considered to be a critical component of the success of this project. In addition, flexibility in deploying approved funding by the Government is also considered an important factor, enabling Government and the beneficiary enterprises to conclude phase out of CFCs in pharmaceutical MDIs in a timely manner while protecting patients' interests and needs.

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LIST OF ABBREVIATIONS

CDSCO	Central Drugs Standard Control Organization
CFC	Chloro Fluoro Carbons
CP	Country Programme
CTC	Carbon Tetra Chloride
ExCom	Executive Committee of the Multilateral Fund
DPI	Dry Powder Inhaler
GWP	Global Warming Potential
GTZ	Gesellschaft für Technische Zusammenarbeit, Germany
HCFCs	Hydrochlorofluorocarbons
HFA	Hydro Fluoro Alkanes
IA	Implementing Agency
MDI	Metered Dose Inhaler
MLF	Multilateral Fund for the Implementation of the Montreal Protocol
MOEF	Ministry of Environment and Forests, Government of India
MP	Montreal Protocol
MT	Metric Tonnes
ODP	Ozone Depleting Potential
ODS	Ozone Depleting Substances
SMEs	Small and Medium-sized Enterprises
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

1. INTRODUCTION

1.1 BACKGROUND OF CFC CONSUMPTION, PRODUCTION AND PHASE-OUT

India became a party to the Vienna Convention on 19 June 1991 and acceded to the Montreal Protocol on Substances that Deplete the Ozone Layer on 17 September 1992. Table-1 shows the dates of ratification by India of the Protocol and its amendments. Since the annual calculated consumption of controlled substances in India, listed in Annex-A of the Montreal Protocol, was less than 0.3 kg per capita, India was classified as a party operating under Paragraph-1, Article-5 of the Montreal Protocol and thus qualified for technical and financial assistance, including transfer of technology, through the financial mechanism of the Montreal Protocol.

Table-1: India - Dates of Ratification of Montreal Protocol and Amendments

Agreement/Amendment	Date of Ratification
Vienna Convention	19 June 1991
Montreal Protocol	17 September 1992
London Amendment	17 September 1992
Copenhagen Amendment	03 March 2003
Montreal Amendment	03 March 2003
Beijing Amendment	03 March 2003

India's Country Programme for phase-out of ozone depleting substances under the Montreal Protocol was finalized in August 1993 with the assistance of United Nations Development Programme (UNDP), The Energy and Resources Institute (TERI) and representatives of various ministries, industries and scientific institutions. The Country Programme was submitted to and approved at the 11th Meeting of the Executive Committee of the Multilateral Fund for Implementation of the Montreal Protocol, in November 1993.

India's first Country Programme Update was carried out during 2003-2006 and was submitted to and approved at the 49th Meeting of the Executive Committee in July 2006. Among the key tasks identified for the future of the Montreal Protocol programme in India, were completion of all ongoing CFC and CTC phase-out activities in various sectors by 2010, combating illegal trade in CFCs and fine-tuning ODS regulations for sustained compliance and long term management of HCFCs.

Since the approval of the original Country Programme for Phase-out of Ozone Depleting Substances in 1993, India has made significant progress in controlling the production and consumption of ODS. From a consumption level of 10,370 metric tonnes of ODS in 1991, the unconstrained demand was forecasted at about 96,000 metric tonnes by 2005.

The actual consumption of ODS by end-2006 was less than 2,000 metric tonnes annually. These reductions were achieved through technical and financial assistance from the Multilateral Fund, support from implementing agencies in implementation of approved projects and activities and due to proactive policy and regulatory actions by Government of India.

Table-2 below summarizes approved ODS phase-out activities, both completed and ongoing, in various sectors:

Table-2: Summary of ODS Phase-out Activities in All Sectors (as of end-2006)

Sector	Number of Projects	Funding (US$)	Phase-out (ODP tonnes)
Aerosols Sector	27	3,227,739	689
Foams Sector	159	34,785,641	4,373
Firefighting Sector (Halons)	18	2,458,701	2,162
Refrigeration & Air Conditioning Sector	49	32,254,823	3,203
Solvents Sector	41	61,358,042	12,966
Production Sector (including Halons)	2	84,600,000	22,988
Total	**296**	**218,684,946**	**46,381**

Of the above-mentioned activities, over 80% of the activities in terms of ODS phase-out are now completed. All of the individually approved projects have been completed. The implementation of performance-based sector and national-level phase-out plans in the Foams, Refrigeration & Air Conditioning, Solvents and Production sectors is mostly completed, with the respective agreed annual phase-out targets met or exceeded so far.

Three main national/sector-level ODS phase-out activities, governed by multi-year performance-based agreements between Government of India and the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, are currently under implementation:

NCCOPP (National CFC Consumption Phase-out Plan)

This project combines the CFC phase-out activities in the Foams, Refrigeration (Manufacturing) and Refrigeration (Servicing) Sectors, into a single agreement beginning March 2004. The agreed annual consumption and phase-out targets under the NCCOPP are as below:

Table-3: Agreed Annual CFC Consumption & Phase-out Targets under NCCOPP from 2004-2010

Year	2004	2005	2006	2007	2008	2009	2010
ODS Consumption limit (ODP tonnes)	3,489	1,814	960	464	317	172	
ODS Phase-out (ODP tonnes)	1,675	854	496	147	145	172	0

From 2007, the phase-out activities under the Foam Sector and Refrigeration (Manufacturing) Sectors are completed, and the focus of the NCCOPP is predominantly on building sustainable infrastructures to progressively reduce demand for CFCs in the Refrigeration (Servicing) Sector and transition to zero-ODP alternatives. The key challenges identified are as below:

- Availability of adequate CFCs for legitimate servicing needs beyond 2010, through stockpiling, recovery/recycling and reclamation
- Accelerating retrofitting/replacement of CFC-based equipment to reduce dependence on CFCs for servicing
- Adequate capacity building and awareness at the field-level service establishments and technicians to minimize CFC emissions and losses

Intensive monitoring of the investment, technical assistance, training and capacity building components would be needed to ensure that India complies with the agreed phase-out targets.

CTC Phase-out Plan

The project addresses the production and consumption of non-feedstock CTC. The agreed annual production and consumption targets are as below:

Table-4: Agreed Production and Consumption Targets under CTC Phase-out Plan

Consumption/Year	2005	2006	2007	2008	2009	2010
Maximum Consumption (ODP MT)	1,726	1,147	708	268	48	0
Maximum Production (ODP MT)	1,726	1,147	708	268	48	0

The implementation of this project is underway. The key challenges identified are as below:

- Adequate assistance to small scale CTC users in the textile and metal cleaning industry, including cost-effective availability of substitutes
- Ensuring timely phase-out of CTC in the large users in the process agent and solvents sectors

Intensive monitoring of the investment, technical assistance, training and capacity building components would be needed to ensure that India complies with the agreed phase-out targets. Appropriate institutional arrangements are in place to address the additional obligations such as performance verification and reporting.

Production Sector Gradual Phase-out Plan

This agreement is in place since 1999. The agreed annual limits on CFC production are shown in Table-5 below:

Table-5: Agreed Maximum Allowable CFC Production Levels from 1999-2010

Year	Production (metric tonnes)	Year	Production (metric tonnes)
1999	22,588	**2005**	11,294
2000	20,706	**2006**	7,342
2001	18,824	**2007**	3,389
2002	16,941	**2008**	2,259
2003	15,058	**2009**	1,130
2004	13,176	**2010**	0

Mechanisms for monitoring, reporting and verification as per the agreed protocols are already established and would continue to be implemented. So far India has complied with all provisions of the agreement governing this project.

At the 54th Meeting of the Executive Committee in April 2008, India agreed to cease its production of CFCs from 01 August 2008, over a year in advance of the earlier agreed closure date. In accordance with Decision 54/35, India can produce a maximum of 690 metric tonnes of CFCs until 01 August 2008, primarily for use in manufacturing of CFC-based MDIs. An additional quantity of 135 metric tonnes of CFCs can be used from existing stocks after reprocessing, for manufacturing CFC-based MDIs. The Indian producers also would need to export 1,228 metric tonnes of CFCs prior to 31 December 2009.

1.2 CFC CONSUMPTION TRENDS IN MDI MANUFACTURING

There are currently five manufacturers of MDIs in India (more details on these manufacturers are provided ensuing chapters). The production of MDIs has grown significantly in India in recent years, increasing from about 29 million units in 2003 to about 55 million units in 2007.

The pharmaceutical grade CFCs needed for manufacturing CFC-based MDIs are sourced from both domestic CFC producers and through imports. Table-6 below shows the source of CFC consumption in MDI manufacturing in India from 2003 onwards:

Table-6: CFC Consumption in MDI manufacturing in India

CFC Consumption/Year	2003	2004	2005	2006	2007
Consumption (ODP tonnes)	578.91	742.81	740.41	763.62	608.07
Sourced indigenously (ODP tonnes)	578.91	742.81	683.41	591.12	505.47
Sourced through imports (ODP tonnes)	0.00	0.00	57.00	172.50	102.60

While examining the consumption trends for CFCs in India in general and in the MDI manufacturing in particular, the following factors need to be carefully considered:

(a) It would be useful to note that during the preparation of the National CFC Consumption Phase-out Plan (NCCOPP), *the consumption of CFCs in the MDI manufacturing sub-sector was not reported and therefore not taken into account*.

(b) The consumption in the Refrigeration and Air Conditioning Servicing Sector, as reported in the CP progress data reporting was 1,105 ODP tonnes in 2006. While this was below the agreed consumption limit of 1,147 ODP tonnes for 2006 and while it is being addressed through ongoing activities under the NCCOPP, it is evident that the CFC consumption in MDI manufacturing for 2006 (700.02 ODP tonnes) as reported in the CP progress data reporting, constitutes a significant part of the overall national consumption and presents a challenge for future compliance.

(c) Against the backdrop of ExCom Decision 54/35, which stipulates a limit on availability of CFCs for consumption in India, i.e., a maximum of 825 ODP tonnes would be available for consumption during 2008 and 2009, there would be an inevitable "competition" between the needs for CFCs in MDI manufacturing and the needs of the Refrigeration and Air Conditioning Servicing Sector. This situation introduces a peculiar and delicate challenge for designing appropriate policies and regulations to carefully balance the legitimate needs of SMEs in the Refrigeration and Air Conditioning Servicing Sector and the justifiable health needs of vulnerable asthma and COPD patients. Economical access to proven and effective drugs needs to be maintained in a developing country such as India and would remain the cornerstone of future regulatory and policy interventions.

(d) While the consumption of CFCs in MDI manufacturing shows a decline from 2006 to 2007, it still constitutes a significant portion of the agreed allowable total consumption and significantly in excess of the agreed consumption limits in 2008 and 2009. This situation poses a significant risk of non-compliance post-2007 and calls for urgent interventions to ensure timely and smooth transition to non-CFC MDI manufacturing.

2. SITUATION ANALYSIS

2.1 COUNTRY BACKGROUND

2.1.1 Geography and Demographics

Located in South Asia, India is the seventh-largest country by geographical area and the second most populous country in the world. India has a coastline of over 7,000 km, bounded by the Indian Ocean on the south, the Arabian Sea on the west, and the Bay of Bengal on the east. India borders Pakistan to the west; People's Republic of China, Nepal and Bhutan to the north-east; and Bangladesh and Myanmar to the east.

India has a population of about 1.1 billion (2006), comprising approximately one-sixth of the world's population. India occupies 2.4% of the world's land area, but supports over 16% of the world's population and 21% of the world's global burden of disease. Almost 40% of Indians are younger than 15 years of age. About 70% of the people live in more than 550,000 villages, and the remainder in more than 200 towns and cities. The standard of living in India is projected to rise sharply in the next half-century; it currently battles high levels of poverty, persistent malnutrition, and environmental degradation.

The weather conditions in India are strongly influenced by the Himalayas in the north and the Thar Desert in the northwest. Meteorologists divide the year into four main seasons for most of the country: monsoon, summer, winter and a mild autumn.

India is categorized as a tropical country with high propensity to infectious diseases. These include food or waterborne diseases such as bacterial diarrhea, hepatitis A and E, typhoid, vector borne diseases such as dengue and malaria, water contact diseases such as leptospirosis and animal contact disease such as rabies. The geographical spread of the country frequently affected by floods and storms and low levels of per capita income with significant poverty particularly in rural areas, essentially drive the need for extensive and affordable healthcare solutions. WHO in their Country Cooperation Strategy Brief has indicated that India is experiencing high growth in tuberculosis and chest related diseases.

2.1.2 Asthma and COPD in India

Asthma and Chronic Obstructive Pulmonary Disease (COPD) are considered a serious health problem worldwide owing to their magnitude in terms of morbidity, mortality and disability especially in ill-managed patients. Their impact on patients and their relatives as well as consequent social costs, underline the need for comprehensive and coordinated responses.

COPD is a significant health problem in India. Among the non-communicable diseases, bronchial asthma is considered to be one of the leading causes of hospital admissions in India. The economic and social cost of this disease is sizeable due to the disabling effect associated with frequent episodes of decompensation.

Given the size of the country and its population and given the geographic and socio-political diversity in India, collection of reliable national statistics on diagnosis and management of diseases is an enormously challenging and expensive proposition. However, some indicative statistics can be presented.

From a 1996 survey, COPD was prevalent in 7.7% of the population in India. The estimated number of adult patients of age 30 or more was 12.36 million. More recent studies estimate about 15 million persons affected by asthma in India.

Data from a few population-based studies in adults has recently become available. In a study conducted as part of the European Community Respiratory Health Survey in 2000, asthma prevalence in adults aged 20-44 years in India was reported to be 3.5% using 'clinician diagnoses' and 17% using a broader definition (which included a prior physician diagnosis and/or a positive bronchioprovocation test).

Studies on mortality and morbidity from Acute Respiratory Infections (ARI) in India indicate that ARI is the most significant cause of child mortality.

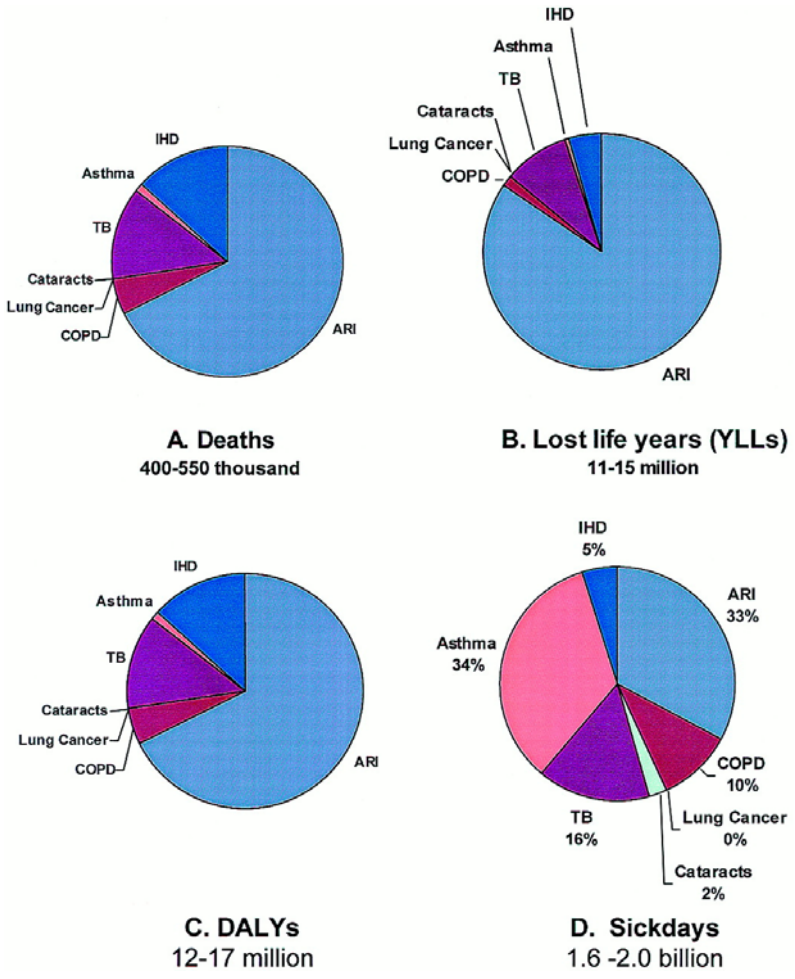


Figure-1: Annual Health Burden from Indoor Air Pollution in India
(Source: School of Public Health, University of California – Berkeley, 2000)

Figure-1 above indicates the incidence and contribution of respiratory disorders including Asthma, COPD, tuberculosis, ARI, etc. to the national health burden from Indoor Air Pollution in India.

2.1.3 Treatment

The most preferred route for therapeutic administration of drugs into lungs for respiratory disorders, on which there is international consensus by health authorities, is inhalation. Inhalation therapy with aerosols allows achieving high concentration of drugs such as corticosteroids, beta adrenergics and anticholinergics in airways, while diminishing their adverse side effects when used through other routes of administration. The treatment generally requires a regular administration of one or more drugs through metered dose inhalers (MDIs) or in some cases dry powder inhalers and less frequently through nebulizers. Inhalation treatment is administered by metered-dose inhalers that represent almost 70% of prescribed inhalers. The remaining 30% are dry powder inhalers and small quantity of nebulizers.

The most widely used propellants for metered dose pharmaceutical aerosols in India are CFCs. CFCs are non-toxic, non-reactive and non-flammable, with no odor, no flavor and excellent solvent action. Since CFCs will need to be phased out from 2010, alternative propellants, mainly HFAs, have been introduced in the past decade or more to replace CFCs and have already cleared clinical testing for several formulations.

The main categories of drugs used for treatment of Asthma and COPD are as below:

Category A: Short-acting beta-antagonist bronchodilators such as Salbutamol, Terbutaline and Fenoterol

Category B: Steroids such as Beclomethasone, Budesonide and Fluticasone

Category C: Non-steroid anti-inflammatory agents such as Disodium Cromoglycate and Nedochromil

Category D: Anti-cholinergic bronchodilators such as Ipratropium and Oxytropium

Category E: Long-acting beta-antagonist bronchodilators such as Salmeterol and Formoterol

Category F: Combination of products with two or more active ingredients.

MDI usage in India has seen a significant increase in the last decade. Initially, MDIs were prescribed by medical practitioners as a “last resort” solution possibly due to lack of awareness and limited availability of the product. With time and due to promotion efforts undertaken by the pharmaceutical industry and asthma associations, the adoption of MDIs as a treatment option for respiratory disorders has increased. As per industry estimates, asthma and COPD are prevalent in about 100 million people in India (about 10% of the population of the country). In addition, patients suffering from other diseases of the throat and other respiratory ailments, also use MDIs. Thus, cost effective availability of MDIs and/or similar solutions is critical for a country like India.

The MDI usage in India is predominantly in urban areas. However, the Ministry of Health and Family Welfare launched a National Rural Health Mission (2005-2012) which involves expansion of public expenditure on rural health care delivery for improved access to healthcare for rural populations particularly women, children and economically disadvantaged persons. Through the NHRM, medical drugs and devices are provided at subsidized costs or no costs to such patients, thus resulting in an increase in the number of patients gaining access to remedies such as MDIs particularly in the rural areas. This has contributed to the significant increase in MDI production over the past few years.

2.2 INSTITUTIONAL FRAMEWORK

2.2.1 Institutional Arrangements for the Montreal Protocol

Government of India has designated the Ministry of Environment & Forests as the national coordinating body for the Montreal Protocol in India. The functions and responsibilities of the Ministry of Environment & Forests as the designated national authority and nodal ministry include notification of regulations pertaining to the Montreal Protocol, issues related to international cooperation, maintaining and managing data on production, imports, exports and consumption of ODS, monitoring of implementation of Montreal Protocol activities, interacting with other line ministries on technical and financial matters pertaining to implementation of activities, liaising with scientific, technical and other public institutions for technical matters, representing India at various multilateral meetings and discussions, etc.

The Ministry of Environment & Forests has since 1991, established a special directorate (Ozone Cell) within the Ministry, which is the focal point for managing and coordinating the implementation of the Montreal Protocol activities in India.

The Ministry of Environment & Forests has also created an Empowered Steering Committee (ESC) with the approval of the Cabinet, which is an apex body mandated for formulation and review of policy actions for Montreal Protocol implementation. The ESC is assisted by three standing committees, for advice on Technology and Finance, Small-scale Industries and Monitoring/Evaluation.

Figure-2: Institutional Arrangements for the Montreal Protocol in India

The Ozone Cell established a Project Management Unit (PMU) for implementation of the CFC Production Sector Phase-out Project in February 2002. The functions of the PMU include implementation and review of ODS phase out plans, assisting Ozone Cell in monitoring and implementation of ODS phase out activities, monitoring the production quota and export licensing systems, coordination of training, seminars and awareness activities for various stakeholders, etc. The governing body of the PMU consists of Additional Secretary (MOEF) as President, Joint Secretary (MOEF) as Vice-President, representatives from Department of Chemicals and Fertilizers, Ministry of Commerce and Industry, Confederation of Indian Industry (CII), Director-General Foreign Trade with Director–Ozone Cell and Joint Director-Ozone Cell as members.

Figure-2 above depicts the organizational and institutional structure of management of the Montreal Protocol in India.

2.2.2 Institutional Arrangements related to pharmaceutical MDIs

The Ministry of Health and Family Welfare is the nodal ministry designated by Government of India for all matters pertaining to health and family welfare, some of which are notification of regulations pertaining to health, monitoring and controlling drugs, policy matters pertaining to public health and prevention of food adulteration, formulating national health policies, designing and managing national health programmes, medical education and training, international cooperation, etc. The Ministry has administrative control over 29 autonomous/statutory bodies and three public sector undertakings. Figure-3 below shows the organizational arrangement.

The Directorate General of Health Services (DGHS) is an office which serves as a repository of technical knowledge attached to the Department of Health, Ministry of Health and Family Welfare. The DGHS renders technical advice on all medical and public health matters and in the implementation of various health programmes. In order to implement policies and programmes of the Ministry in an effective manner, DGHS is supported by three subordinate offices at various locations in the country.

The Central Drugs Standard Control Organization (CDSCO) functions under the DGHS and is responsible for the approval of licenses for specified category of drugs under the Drug and Cosmetics Act 1940 (updated until 2005). The CDSCO has the mandate to set standards for drugs, cosmetics, diagnostics and devices, approve new drugs and devices, review, approve and conduct clinical trials, regulate the standards of imported drugs, screen drug formulations, monitor adverse drug reactions, control quality of imported drugs, coordinate activities of state-level organizations and provide expert advice with a view to bring about uniformity in the enforcement of the Act. The CDSCO also provides guidance on technical matters, conducts training programmes for regulatory and enforcement officials and analysts and publishes the Indian Pharmacopeia.

The CDSCO is administered by the Drugs Controller General of India and is supported by four zonal offices, three sub-zonal offices and seven offices at ports of entry. In addition, CDSCO also operates six laboratories for quality control and testing of drugs.

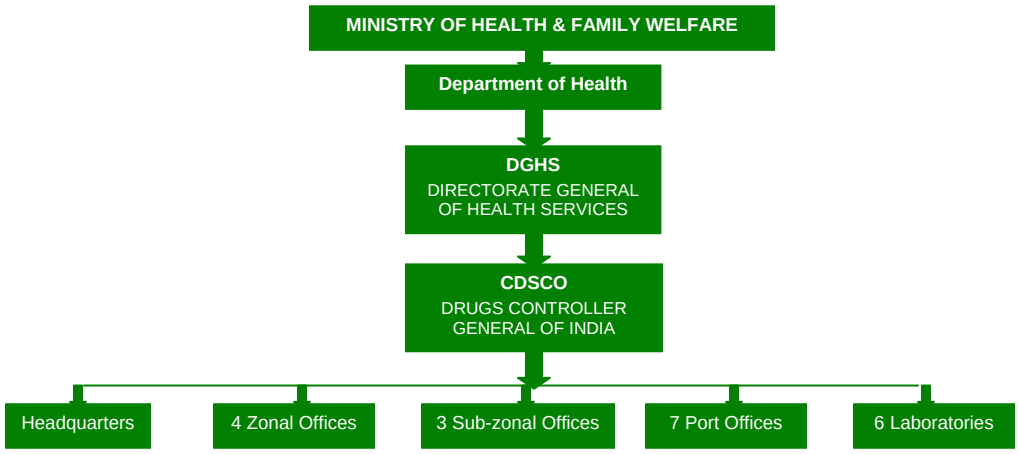


Figure-3: Institutional Arrangements for Drugs in India

2.2.3 Policies and Regulations

Policies and Regulations pertaining to Montreal Protocol

India's Country Programme for phasing out ODS, established the following guiding principles reflecting national priorities for formulating appropriate policy and regulatory instruments:

- To strengthen national institutions for monitoring and managing the ODS phase-out, and formulation and implementation of appropriate policies.

- To assist indigenous industries for conversion to non-ODS technologies through the Montreal Protocol financial mechanism, while ensuring that the SMEs and other unorganized tiny enterprises are fully compensated for conversions, including retraining

- To minimize economic dislocation either through closure of manufacturing units, loss of productive capacity, or through major capital expenditure that could become obsolete in future.

- To maximize indigenous production by encouraging technology transfer for and local production of non-ODS substitutes

- To give preference to one-time replacements

- To minimize obsolescence costs by promoting recycling, retrofitting and drop-in substitutes to prolong economic life of existing equipment, until new replacement technologies become mature, cost-effective and available

- To institute decentralized management of ODS phase-out activities and arrangements to facilitate feedback for smooth implementation.

- To facilitate development of new standards and certification systems for products and processes including those for safety

- To integrate the ODS phase-out activities closely with the growth in the various industrial sectors, economic reforms, etc.

- To evaluate alternatives to ODS and the available substitute technologies on a continuing basis, so as to lead to wider adaptation and dissemination.

- To periodically reassess and revise the Country Programme to reflect technological developments, progress in implementation of ODS phase-out activities and evolving trends in the growth of the various industrial sectors.

Recognizing the importance of establishing an effective regulatory framework for the successful implementation of the Montreal Protocol Programme and consistent with the guiding principles for developing policies, MOEF initiated actions to create one of the most comprehensive and forward-looking regulatory frameworks in the world, to support the various ODS phase out measures in India.

In exercise of the powers conferred by sections 6, 8 and 29 of the Environment Protection Act of 1986, Government of India notified the Ozone Depleting Substances (Regulation and Control) Rules 2000, which formally came in to effect from January 2000. The provisions of this comprehensive legislation are summarized as below:

General

- Every entity that produces, uses, imports, sells, stocks, reclaims or destroys ODS has to maintain records and file reports as specified.
- Every entity, which has received technical and/or financial assistance from any international agency or financial assistance from Government of India including duty exemptions, is required to maintain records and file reports as specified.
- Mandatory registration for reclamation and destruction of ODS. All registrations will be valid for specified periods, after which, they are required to be renewed.

ODS Production

- Mandatory registration with MOEF
- Restriction on production levels as per "base level" and specified time-bound reductions.
- Prohibition on creating new capacity or expansion of capacity

ODS Consumption

- Ban on new capacity or expansion of capacity for production of ODS-based equipment.
- Mandatory registration with designated authorities
- Declaration requirement in prescribed format at the time of procurement of ODS
- Restrictions on production of ODS-based products in various sectors from 2003

ODS Trade

- Mandatory registration for exporters & importers with designated authorities
- Import of ODS and ODS containing equipment only against license
- Export restricted to countries who are signatory to the Montreal Protocol against quota
- Trade in controlled substances with countries not party to the Montreal Protocol is prohibited.
- The export of Annex-A and Annex-B substances to Non-Article-5 Parties is prohibited.
- The import and export of all Annex-A and Annex-B substances are subject to licensing.
- Import of Equipment containing ODS was subjected to licensing

Fiscal Incentives

- Full exemption from Customs and Excise tariffs on capital goods required to implement ODS phase out projects. Duty exemptions also extended to capital goods required for establishing new capacity with non-ODS technology.
- Indian financial institutions were advised not to finance/refinance new ODS producing/consuming enterprises. The Tariff Advisory Committee (a statutory body under the Insurance Act, 1938) advised to grant suitable discounts on fire insurance premiums if alternative agents are used to replace Halons.

Policies and Regulations pertaining to pharmaceutical MDIs

The National Health Policy of 2002 (NHP) prioritizes key policy actions focusing on:

- Eradication measures for diseases such as polio, leprosy, black fever and filariasis, mortality reduction of 50% due to vector/water-borne diseases and achieve zero growth in HIV aids
- Establish an integrated network for health surveillance, national health accounts and health statistics
- Establish a comprehensive network of primary healthcare facilities linked to health education and encompassing a referral system
- Expand public health services and affordable and equitable access to drugs and devices through promotion of indigenous generic drugs and vaccines
- Establish uniform standards for deployment of healthcare personnel and extend continuing education and retraining facilities for healthcare personnel
- Intensify dissemination and awareness programmes for health-related information
- Promote medical research on therapeutic drugs and vaccines for tropical diseases
- Establish regulatory mechanism to ensure quality and standards in private sector healthcare
- Promote and increase involvement of civil society in disease control and healthcare
- Efficient regulation and enforcement of quality standards for drugs

At present the following laws and the regulations made thereunder, govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India.

- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
- The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act)

In addition, there are some other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India. The important ones are:

- The Industries (Development and Regulation) Act, 1951
- The Trade and Merchandise Marks Act, 1958
- The Indian Patent and Design Act, 1970
- The Factories Act

The primary law in India concerning pharmaceutical MDIs is the Drugs and Cosmetics Act 1940 (amended up to 2005). Some of the key features of the rules and regulations notified under this Act and pertaining to pharmaceutical MDIs are as below:

General

- The competent licensing authority is the Drugs Controller General of India (DCGI)
- Special committees comprising of subject experts and DCGI representatives will be set up for evaluation of the concerned devices and the committees are empowered to formulate their own benchmarks and procedures for such evaluation and for standards to which such devices should conform.

Imports

- Import is subject to licensing and no import shall take place prior to issuance of license

Manufacturing

- Manufacturing is subject to licensing and no manufacturing can take place prior to issuance of the license
- Applicants shall provide complete information on the details of the product and manufacturing to the licensing authority
- For new products or products without benchmark certification, Expert Committees will be set up for evaluation and assessment. The Committee(s) will submit their report and recommendation to the licensing authority
- In the event of approval, the state-level authorities will carry out a joint inspection and verification, after which the license may be issued

Registration for Manufacturing and Import

- A registration certificate in respect of the product and premises in which it is manufactured is required and the application for this certificate needs to be made to the competent authority by the manufacturer or importer along with required information and fees
- Registration is required separately for each medical device which has a different material, ingredient and/or a method of use
- Registration can be subject to such conditions as may be applied by the competent authority
- Registration is normally valid for five years and is renewable, unless canceled earlier.

Sale

- Sale of such medical devices requires a license and no sale shall be carried out prior to issuance of a license

2.3 MDI MANUFACTURING IN INDIA

2.3.1 CFC-based and HFA-based MDI manufacturing

There are currently five manufacturers of pharmaceutical MDIs in India. Table-7 below shows the MDI production levels in India from 2003 to 2007:

Table-7: MDI Manufacturing in India (2003-2007)

Manufacturer	Total Production (in million units)				
	2003	2004	2005	2006	2007
CFC-based MDIs					
Cadila Healthcare Ltd.	Blanked for reasons of confidentiality				
CIPLA Ltd.					
GlaxoSmithKline Pharmaceuticals Ltd.					
Midas-Care Pharmaceuticals Ltd.					
Sun Pharmaceutical Industries Ltd.					
Sub-total (CFC-based MDIs)	28.83	35.69	31.77	39.16	31.19
HFA-based MDIs					
CIPLA Ltd.	Blanked for reasons of confidentiality				
Midas-Care Pharmaceuticals Ltd.					
Sun Pharmaceutical Industries Ltd.					
Sub-total (HFA-based MDIs)	0.47	1.23	4.06	11.19	24.32
Grand Total	29.30	36.92	35.84	50.35	55.51

Figure-4 below depicts the production volumes of CFC and HFC-based MDIs in India during 2003 to 2007:

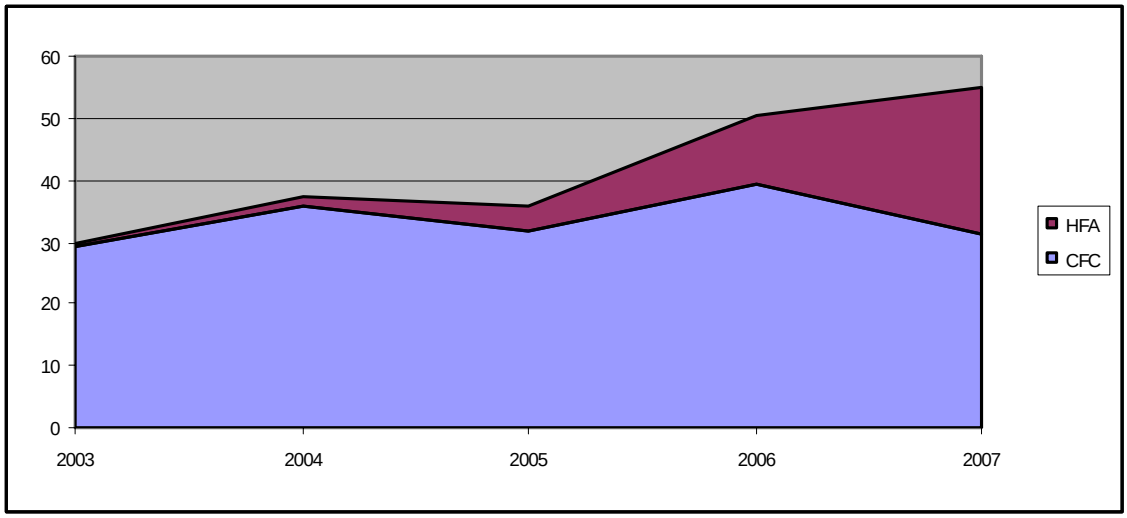


Figure-4: CFC-based and HFC-based MDI production in India (2003-2007)

As seen in the table and graphic above, there is a clear growth in demand for MDIs in India in the past few years. The growth is likely due to more widespread use of MDIs in the asthma and COPD patient population which is consistent with global trends. While the share of HFA products is growing in number of units produced, only two of the seven manufacturers have developed HFA formulations for a limited number of drugs. This implies that there is still a major work in formulation, development and registration of new HFA products for the coming years. Given the limitation on availability of CFCs in the near future, the majority of the companies are in the need to have these products commercially available as soon as possible.

In response to the control measures established by the Montreal Protocol, MDI manufacturers in India have already initiated a process to identify alternatives to CFC-based MDIs. Some of them have been able to formulate some products based on HFA after significant investments on research and development. However, challenges to offer HFA-based MDIs exist, due to a combination of reasons which include higher costs of production, low availability of materials, higher cost of equipment, lost of production capacity and restrictions on the retail price of the products under the Drug Price Control Order, which makes it difficult for manufacturers to recover the additional costs. There are still many products being produced with CFCs and there will be need for CFCs in the next few years.

It takes between 9 months and two years to develop a new formulation that includes planning, formulation development, scale-up and stability testing. Based on the regulatory framework, the time needed for registering a new product can vary from 6 months to a year. Thus the overall timeframe for introducing new products in the market takes between 15 months and three years.

Considering the above background, it is possible to appreciate the constraints in context of demand growth, time, resources, regulatory framework and pricing maneuverability faced by MDI manufacturers in India in transitioning from CFC-based MDIs to non-CFC or HFC-based products.

2.3.2 Domestic Sales and Exports of CFC-based MDIs

A portion of the total CFC-based MDIs produced in India is exported to both non-Article-5 and Article-5 countries. Table-8 below shows the quantities of CFC-based MDIs for the domestic market and exports in recent years:

Table-8: Domestic Sales and Exports of CFC-based MDIs

Parameter	Total (in million units)				
	2003	2004	2005	2006	2007
Total Domestic Sales	14.90	15.72	16.21	18.27	10.33
Exports to non-Article-5 countries	0.42	0.05	0.42	0.47	1.53
Exports to Article-5 countries	13.52	19.93	15.16	20.43	19.30
Total Exports	13.94	19.98	15.57	20.90	20.82
Total Production	28.83	35.69	31.77	39.16	31.19
Exports to non-Article-5 countries (% of total)	1.5%	0.1%	1.3%	1.2%	4.9%

It is seen from the above that before 2007 exports of CFC-based MDIs to non-Article-5 countries were around 1% of the total production. Only in 2007 exports increased to a level that constituted 4.9% of the total production of CFC-based MDIs. Only one of the enterprises (CIPLA) is exporting to Non-Article 5 countries.

2.3.3 Breakdown of CFC Consumption in MDI manufacturing by enterprise

The CFCs required for the MDIs manufactured in India are sourced from domestic CFC producers as well as imported from other countries. Table-9 below shows the consumption of CFCs in MDI manufacturing in India in recent years for each manufacturer:

Table-9: Breakdown of CFC Consumption in MDI manufacturing by enterprise (2003-2007)

Manufacturer	CFC Consumption (ODP tonnes)				
	2003	2004	2005	2006	2007
Cadila Healthcare Ltd.	Blanked for reasons of confidentiality				
CIPLA Ltd.					
GlaxoSmithKline Pharmaceuticals Ltd.					
Midas-Care Pharmaceuticals Ltd.					
Sun Pharmaceutical Industries Ltd.					
Total	**578.91**	**742.81**	**740.41**	**763.62**	**608.07**

Figure-5 below depicts the relative CFC consumption of the five MDI manufacturers (2007):

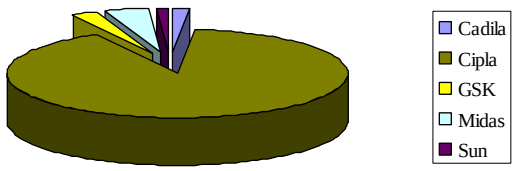


Figure-5: Relative CFC Consumption of the MDI manufacturers (2007)

2.3.4 Industry Structure

India caters to the needs of inhalation therapy for patients suffering from asthma, COPD and other respiratory ailments, through an established local MDI manufacturing capacity, which provides affordable MDI products to these patients. All MDIs consumed in India are locally manufactured.

The MDI manufacturing industry in India has experienced a growth of about 15-20% annually in the past decade. In 2007, over 50 million units of MDIs were sold in India, which has a population of about 1.1 billion and a patient base of about 15-20 million. Yet, the per capita use of MDIs in India is quite low, as compared to for instance UK, where over 60 million units of MDIs were sold for a population of 60 million and a patient base of about 6 million. This implies that that production of MDIs in India will continue to grow to provide affordable access to MDIs to the large number of asthma and COPD patients.

There were historically a total of seven MDI manufacturers in India. Of these, AstraZeneca Pharma India Ltd. has 100% non-Article-5 ownership and sub-contracts its products to one of the other manufacturers. Natco Pharma Ltd., an indigenously owned enterprise, has ceased production of MDIs as of 2007. Thus, currently five manufacturers of MDIs are operational in India. Table-10 below shows the MDI production breakdown by enterprise in India in 2007:

Table-10: MDI production breakdown by enterprise (2007)

Manufacturer	Total MDI production in 2007 (million units)	Share of total production
Cadila Healthcare Ltd.	Blanked for reasons of confidentiality	
CIPLA Ltd.		
GlaxoSmithKline Pharmaceuticals Ltd.		
Midas-Care Pharmaceuticals Ltd.		
Sun Pharmaceutical Industries Ltd.		
Total	55.51	100.0 %

Figure-6 below depicts the total production of MDIs and respective manufacturer shares pictorially:

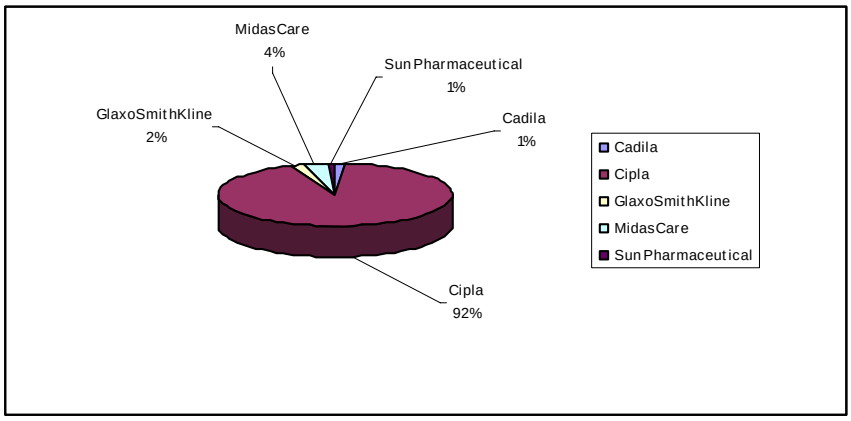


Figure-6: MDI Production breakdown by enterprise in 2007

Table-11 below shows the baseline information and products manufactured by these enterprises:

Table-11: Baseline Data for MDI manufacturers in India

PARAMETER	ENTERPRISE DATA				
	Cadila Healthcare Ltd.	**CIPLA Ltd.**	**GlaxoSmithKline Pharmaceuticals Ltd.**	**Midas-Care Pharmaceuticals P. Ltd.**	**Sun Pharmaceutical Industries Ltd.**
Indigenous Ownership (%)	100	100	49.33	100	100
Date of Establishment	1952	1935	1924	1986	1983
Number of MDI plants	1	3	1	1	1
Number of production lines for CFC-based MDIs	1	7	1	2	1
Date of establishment of CFC-based MDI capacity	2002	1995 -2002 - 2003	1989	1993-1994	1999-2000
Lines Output	25 – 28 can/min	455 can/min CFC + 160 can/min HFA	32 can/min	24 – 26 can/min	20 – 23 can/min
Annual capacity of CFC-based MDI production (based on single shift and 240 working days/year)	2.5 – 2.8 million	42 million CFC + 6 million HFA	3.3 million	3.38 million*	1.9 – 2.1 million
Products manufactured (strengths)	1 Salbutamol (1) 2 Budenoside (2) 3 Formoterol Fumarate (1) 4 Ipratropium Bromide (1) 5 Budenoside + Formoterol Fumarate (3) 6 Salbutamol+ Ipratropium Bromide (1) 7 Salmeterol + Fluticasone Propionate (3) 8 Tiotropium Bromide (1) 9 Tiotropium Bromide + Formoterol Fumarate (1) 10.Formoterol Fumarate + Fluticasone Proppionate(2)	1 Isoprenaline Sulphate (1) 2 Beclomethasone Nasal (1) 3 Sodium Cromoglicate (2) 4 Ipratropium Bromide (2) 5 Ipatropium + Salbutamol (1) 6 Tiotropium Bromide (1) 7 Tiotropium Bromide + Formoterol (1) 8 Levoalbuterol (1) 9 Levalbuterol + Ipatropium (1) 10 Belcomethasome + Formoterol (2) 11 Salbutamol (1) 12 Beclomethasone (4) 13 Salbutamol + Beclomethasone (1) 14 Budesonide(2) 15 Fluticasone Propionate (4) 16 Salmeterol Xinafoate (1) 17 Formoterol (1) 18 Fluticasone + Salmetrol (3) 19 Budesonide + Formoterol(3) 20 Troventol (1) Ciclesonid. HFA (2) 21 Ciclesonide + Formoterol HFA (2)	1 Salbutamol (1) 2 Beclomethasone (2)	1 Salbutamol (2) 2 Ipratropium Bromide (2) 3 Salbutamol + Beclomethasone(1) 4 Formeterol Fumurate (1) 5 Formoterol + Budesonide (3) 6 Beclometasone (4) 7 Budesonide (3) 8 Salmeterol + Fluticasone (3) 9 Ipratropium + Salbutamol (1) 10 Salmeterol (1) 11 Sodium Cromoglicate (2) 12 Terbutaline (1) 13 Tiotropium Bromide (1) 14 Tiotropium Bromide + Formoterol (1) 15 Levosalbutamol(1) 16 Levosalbutamol + Beclometasone (1) 17 Levosalbutamol + Ipatropium Bromide (1) 18 Ciclesonide (2) 19 Ciclesonide + Formeterol Fumurate (1) 20 Tiotropium + Formoterol + Budesonide (2) 21 Tiotropium +	1 Salmeterol + Fluticasone Propionate (3) 2 Fluticasone Propionate (3) 3 Budesonide (2) 4 Salbutamol (1) 5 Formoterol + Budenoside (3) 6 Tiotropium Bromide (1) 7 Tiotropium Bromide + Formoterol (1) 9 Ciclesonide HFA (2)

PARAMETER	ENTERPRISE DATA				
	Cadila Healthcare Ltd.	**CIPLA Ltd.**	**GlaxoSmithKline Pharmaceuticals Ltd.**	**Midas-Care Pharmaceuticals P. Ltd.**	**Sun Pharmaceutical Industries Ltd.**
		22 Budesonide Formoterol HFA (1) 23 Tiotropium + Formoterol + Ciclesonid. HFA (1)		Formoterol + Ciclesonide (2) 22 Fluticasone (3) 23 Fluticasone + Formoterol (3)	
Total CFC-based products (total strengths)	**10 (16)**	**23 (40)**	**2 (3)**	**23 (42)**	**8 (16)**
Non-Article-5 Exports (2007)	0%	5.6%	0%	0%	0%

* Six working days/week

3. STRATEGY FOR TRANSITION TO NON-CFC MDIS

3.1 INTRODUCTION

3.1.1 Objectives

The main objectives of India's strategy for transition to non-CFC MDIs are:

- To gradually reduce CFC consumption in the manufacture of pharmaceutical MDIs and achieve their complete elimination by 2012.

- To gradually assimilate non-CFC MDI technology into India, so that the required quantities of these products are cost-effectively and sustainably available

3.1.2 Principles

India's strategy to transition from CFC-based MDIs to non-CFC MDIs will be guided by the following key principles, as enunciated in the Country Programme for phasing out of ODS and the National Health Policy:

- The commitment and willingness of Government of India to eliminate substances that adversely affect the environment and ozone layer

- To prevent industrial dislocation and obsolescence, by supporting the indigenous industry to achieve transition through adequate technical and financial assistance

- Equity in health services and cost-effective and continuous availability of MDIs. Therefore, access to MDIs will be protected during the transition period by a gradual substitution that will involve simultaneous availability of CFC and non-CFC MDIs for a period of time under the control and supervision of the CDSCO.

- The transition strategy will be designed and implemented with the participation of a wide range of stakeholders including experts from the clinical sphere, pharmaceutical industry, and health education specialists, who will contribute to the viability and efficient implementation of this project at all the corresponding levels.

- Strengthening of national stakeholder institutions through adequate technical assistance, capacity-building and training

- To formulate and implement policies and regulations that would support the transition

- The acceptability of the CFC-free products and the reduction of the duration of gradual replacement will be encouraged by conducting clinical tests designed to train healthcare professionals and patients in the use of these new products, complemented by targeted awareness actions thus favoring their acceptability during the transition process.

3.2 STRATEGY COMPONENTS

Government of India recognizes that the strategy for transition to non-CFC MDIs in India is a critical step in ensuring compliance with its Montreal Protocol obligations and is therefore committed to take expedited actions to phase-out CFCs in MDI manufacturing in India. Government of India also recognizes the need to align such strategy with the preparedness of its healthcare sector to accept CFC-free alternatives and also the need to ensure adequate and cost-effective availability of MDIs to patients. Based on this the proposed strategy will need to include the following components:

- Technology conversions at MDI manufacturers
- Technical assistance
- Policy and regulatory actions
- Targeted awareness and capacity-building actions among stakeholders
- Efficient management of the transition and implementation of appropriate monitoring and verification protocols

3.2.1 Technology Conversions

This component would cover technology conversions at the five MDI manufacturers in India.

Selection of Technology

In considering options for developing appropriate alternatives to CFC-based MDIs in India, two factors need to be taken into account:

- Ease of use by the patient and applicability to the local context
- Ease of technology conversion
- The requirement to ensure that suitable therapies for all patient groups such as pediatric patients, adolescents and senior patients
- Maturity, effectiveness and commercial availability of the technology

Two main technology options, which qualify based on the above considerations, have been developed as alternatives to CFC-based MDIs. These are:

- HFA technology: This retains the drug delivery mechanism
- Dry Powder Inhalers (DPI): This involves a different delivery mechanism as well as administration of the drug in a different physical form (a powder as compared to an aerosol suspension)

In order to determine which of the above two options is more suited to the Indian context, the relative merits of the two technology options are evaluated.

DPIs

Two of the five MDI manufacturers in India (Cadila and CIPLA), have the facilities to produce single-dose DPIs covering ten drugs. The rationale for developing single-dose DPIs locally was to cover the needs of a specific group of elderly patients who have difficulties in coordination and dexterity to apply MDI products, but not with the intention to replace CFC MDIs as therapeutic treatment for asthma and COPD for all patients. These DPIs did not find acceptability among doctors and patients.
Various problems as reported by the Indian Chest Society and National College of Chest Physicians include:

- Throat irritation and coughing due to higher particle size than in MDIs.

- The tropical climatic conditions in India make it difficult to use the product effectively. At humidity levels of 70% to 80% the capsule absorbs moisture and this prevents the effective separation of the capsule by the device and the delivery of the drug.
- Difficulties in application of the drug include patients swallowing the capsule instead of introducing it in the device. Some of the side effects associated with swallowing the capsule are fatigue, headache, hypertension and growth retardation in children.

It has been very well-documented at the global level that DPIs do not represent a satisfactory therapeutic alternative to pressurized MDIs for all patients or for all drugs. DPI formulations either contain the active drug alone or have a carrier powder (e.g. lactose) mixed with the drug. The drug particles must be of sufficiently small diameter to for deposition on the airways. Young children (typically below 5 years old), patients with severe asthma and elderly COPD patients may not always be able to achieve adequate breathing flow to ensure optimal medication delivery from DPIs. A DPI-only based strategy would leave a significant portion of the patient population at high risk.

HFA-based MDIs

The HFA versions of CFC-based MDIs present an identical delivery mechanism. Therefore no adaptation is required on the part of the patient to use the drug. However, some challenges still exist:

- HFA-based MDIs require acceptance of slightly different physical characteristics with regard to taste.
- The technology of formulation of HFA-based MDIs differs significantly from that of CFC-based MDIs.

Selection of DPIs as an alternative technology will also necessitate providing for costs of access to suitable DPI technology and investments in new manufacturing and packaging infrastructures. Considering the development costs and costs of molds and tooling, the costs per therapeutic dose of DPIs will be significantly higher than those with HFA-based MDIs. Thus, DPI technology is not favorable as a cost-effective alternative.

In consultation with relevant stakeholders and considering the relative merits of the two technology options, it has been decided that HFA technology would be best suited for Indian conditions, considering ease of use for patients, availability of technology and technology providers and wider applicability in a humid climate.

Access to technology

Intellectual property issues are not foreseen, as India does not have to comply with WIPO requirements until 2016, which is beyond the timeframe of this project. Also by that time the patents for the drug molecules involved in this project will have expired. Furthermore, each of the five enterprises currently manufacturing CFC-based MDIs has in-house product development capability that has a record of developing products for the Indian market.

Product Development

Some of the existing CFC-based MDI drugs will need to be reformulated for HFA technology. Others (e.g. Salbutamol plus Ipratropium bromide), which do not have HFA alternative formulations approved will need to be developed. The reformulation and development is expected to be carried out by the enterprises themselves and would be subject to statutory approval. The entire process is expected to take between 9 and 15 months.

Conversions

All five MDI manufacturers utilize CFC pressure filling. They use both CFC-11 and CFC-12 in the manufacture of MDIs. CFC-11 is used for preparation of a "suspension slurry" of the active ingredient to facilitate filling the precise quantity into the open MDI container, after which the MDI container is closed with an aerosol metering valve, and thereafter CFC-12 that acts as the aerosol "propellant" is injected into the aerosol container under pressure through the metering valve. Replacement equipment to allow HFA-based MDI production can be installed alongside existing equipment.

The conversions would involve introduction of the necessary equipment for production lines, suitable for manufacturing the HFA-based MDIs.

More details of enterprise-level technology conversions are provided in Annex-1 and Annex-7.

3.2.2 Technical Assistance

In order to properly coordinate the technical implementation of the strategy, services of external technical expert(s) will be utilized. The tasks would include technical monitoring and supervision of enterprise-level conversions, technical advice on procurement, trouble-shooting issues between enterprises and suppliers, etc. More details are provided in Annex-2.

3.2.3 Policies and Regulations

In order to effectively support the transition to non-CFC MDIs, Government of India proposes to consider the following policy and regulatory interventions:

Control of supply of CFC-based MDIs

- Regulating CFC-based MDI manufacturing beyond 2009
- Regulating new formulations or products with CFC-based MDIs.
- Regulating import of new CFC-based MDIs. The timing of this measure needs to be aligned with the timing of phase-out of CFCs in MDI manufacturing by Ministry of Health and Family Welfare.

Promotion of CFC-free alternatives

- Fiscal incentives for adopting non-CFC alternatives
- Fast track procedures for approval of non-CFC MDIs

More details on this component are provided in Annex-3.

3.2.4 Awareness and Capacity Building Actions

Awareness and capacity-building actions are considered important and complementary to other initiatives to facilitate quicker adoption of HFA-based MDIs. Two critical factors would influence quicker market adoption of HFC-based MDIs:

- Prescription of HFC-based MDIs by doctors
- Wide availability of HFC-based MDIs in pharmacies

The following activities are proposed:

- Stakeholder sensitization workshops at national, regional and local levels
- Development of awareness materials for healthcare professionals, pharmacies, medical facilities treating respiratory diseases and organizations involved in disseminating knowledge on these diseases and treatments
- Public awareness through media publicity
- Color coding/labeling of CFC-based and HFA-based MDIs
- Information dissemination through dedicated website

More information on this component is provided in Annex-4.

3.2.5 Monitoring and Management

Following key activities would be carried out under this component:

a) Coordination of the strategy implementation with the various policy and awareness actions
b) Verification and certification of CFC phase-out
c) Status/progress reporting
d) Monitoring and evaluation of outputs

More details are provided in Annex-5.

Availability and management of Pharma-grade CFCs during the transition period

The consumption of CFCs in MDI manufacturing shows a decline from 2006 to 2007. However, as mentioned in Section 1.2 it still constitutes a significant portion of the agreed allowable total consumption and potentially in excess of the agreed consumption limits in 2008 and 2009. This situation poses a significant risk of non-compliance post-2007 and calls for urgent interventions to ensure timely and smooth transition to non-CFC MDIs and also effective management of CFCs during the transition period.

ExCom Decision 54/35 stipulates a limit on availability of CFCs for consumption in India, i.e., a maximum of 825 ODP tonnes would be available for consumption during 2008 and 2009.

Given these CFC consumption limits, while it is critical to accelerate phase-out of CFCs in pharmaceutical MDIs, it is also critical to ensure availability of adequate pharmaceutical-grade CFCs during the transition period.

In this regard, the following actions are proposed:

- Establishing the requirements of pharmaceutical-grade CFCs needed during the transition period, to ensure reliable availability of proven drugs to patients. This task will be a collaborative effort between the enterprises and government as part of the transition strategy. According to the information collected during the project preparation the quantity required between 2009 and 2012 may be above the 825 ODP tonnes available as per Decision 54/35, but it will need to be accurately defined. For the required quantities above the 825 ODP tonnes available, appropriate steps will need to be defined.

- India may need to apply for Essential Use Nomination for the amount of pharmaceutical-grade CFCs needed, which cannot be covered by the current limitations of availability. The exact amounts required would be calculated as part of the process described above.

3.3 MONITORING MILESTONES

	2008				2009				2010				2011				2012			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Annual CFC phase-out in MDIs (600 tonnes)	**50**				**100**				**150**				**150**				**150**			
Submission of proposal to MLF																				
Approval by MLF																				
Project document signature by Government																				
Implementation appraisal																				
Equipment specifications and approval																				
Equipment procurement and delivery																				
Formulation development																				
Stability testing and laboratory analysis																				
Product registration																				
Policy and regulatory actions																				
Awareness actions																				
Technical assistance																				
Equipment installation and commissioning																				
Trial production																				
Commercial production of non-CFC MDIs																				

3.4 IMPLEMENTATION

The overall management and coordination of the plan will be the responsibility of Ozone Cell, Ministry of Environment and Forests, with the assistance of UNDP as the lead implementing agency, UNEP as the cooperating implementing agency and Government of Italy as the bilateral cooperating agency.

3.5 FINANCING

The total cost of the plan is **US$ 61,701,934**. The requested MLF grant is **US$ 26,759,319**. The balance cost amounting to **US$ 34,942,615** will be co-financed by beneficiary enterprises.

3.6 RESULTS

The plan will result in a sustainable transition from CFC-based to HFA-based MDIs and in a phase-out of CFCs in the manufacture of MDIs in India by 2012.

ANNEX-1

PROJECT COMPONENT-I: TECHNOLOGY CONVERSIONS

ENTERPRISE LEVEL SUMMARIES

ATTACHMENT-1

SUMMARY: CADILA HEALTHCARE LTD.

1. BASIC DATA AT A GLANCE

Local Ownership: 100%
Exports to Non-Article 5 Countries: 0.00
Establishment of Production Line: 2002
Co-financing Commitment: 30%

2. CFC CONSUMPTION

Parameter	CFC-based MDI Manufacturing
	Baseline Year: 2003
CFC Consumed (in ODP Tonnes)	2.94

3. PROJECT COST SUMMARY

The table below shows the summary of the elements of the project and the proposed co-financing, at Cadila Healthcare Ltd (all amounts in US dollars)

Cost Head	Eligible Costs	Proposed Co-Financing	Proposed Project Funding
Incremental Development Costs	840,345	30%	588,242
Incremental Capital Costs	1,218,000	30%	852,600
Incremental Operating Costs	124,842	30%	87,389
TOTAL	**2,183,187**	**30%**	**1,528,231**

4. PROJECT COSTS

4.1 Product Development Costs

In reviewing the extensive listing of Cadila's products, not all of those listed are eligible for consideration. The following will not be eligible or appropriate for consideration.

a) Products which Cadila have decided they do not intend to make available as an HFA MDI and will be discontinued with the phase out of CFC

b) Products launched significantly after the 2003 baseline year. Having reviewed data, some products were under development and in the latter stages of registration in 2003, although are not recorded as formally launched until 2004. These products do represent eligible formulations/ products as significant volumes were manufactured prior to the baseline.

Further, consideration has been given to how products in multiple strengths are typically developed. Where three or four strengths of a product are commercialized, it is typical to develop only the highest and lowest strength in detail and to only undertake minimal confirmatory activities on the intermediate strengths.

Applying these criteria, only 10 formulations out of the 16 existing formulations are included in the calculation of development costs: Salbutamol. Budesonide 100, Budesonide 200, Formoterol Fumarate, Ipatropium Bromide, Budesonide+Formoterol 100, Budesonide+Formoterol 400, Salbutamol + Ipatropium, Formoterol + Fluticasone 125, Formoterol + Fluticasone 250.

Total Cadila Incremental Development Cost is estimated as US 840,345.

4.2 Incremental Capital Costs

Detailed description of the baseline equipment and proposed equipment for conversion can be found in Annex 7. The summary is tabulated below (all amounts in US dollars):

Item	Cost
1 Single Macromat filling line and associated pressure filling and preparation vessel	1,198.000
Modifications to existing area	20,000
Total	**1,218,000**

4.3 Incremental Operating costs

Incremental operating costs are calculated based on 2007 production of CFC-based MDIs. The production in 2007 was 713,387 units. No allowance for future growth in production has been factored. Incremental operating costs are calculated for one year duration.

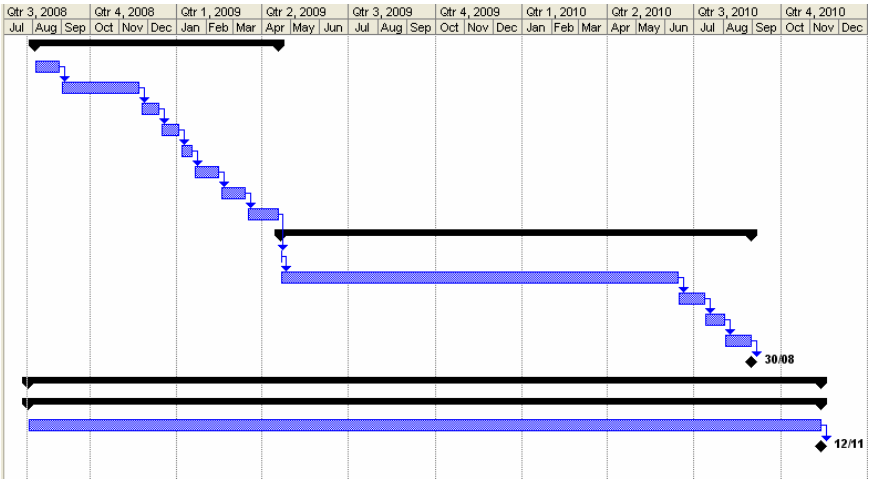
Cadila could not provide a detailed analysis for differences in costs between equivalent CFC and HFA-based MDIs, as they only have CFC-based MDI manufacturing experience. In reviewing the cost quotations provided to Cadila, it is evident that costs and overheads are similar to other enterprises within the sector. It is reasonable therefore to assume that resulting cost differences will also be similar.

Therefore, based on a weighted average calculation, the incremental cost difference between an equivalent CFC and HFA MDI is approximately Indian Rupees 7.37. This is equivalent to US$ 0.175/unit of CFC-based MDI.

Based on the above, the incremental operating costs at Cadila are **US$ 124,842**

5. PROJECT SCHEDULE

	Task Name	Duration
1	**Project Administration**	**185 days**
2	Submission of the project to MLF	4 wks
3	Approval by MLF	3 mons
4	Project document submitted to beneficiarie	3 wks
5	Project document signature	0.75 mons
6	Implementation Appraisal	0.5 mons
7	Selection of team	1 mon
8	Detailed program plaaning	1 mon
9	Generation of equipment TOR's	25 days
10	**Equipment sub Project (Small)**	##########
11	Place order for equipment	1 day?
12	delivery of equipment	15 mons
13	Installation of equipment	4 wks
14	I/Q and O/Q	3 wks
15	PQ	4 wks
16	Equipment available	0 days
17	**Formulation Development sub project**	**600 days**
18	**Pilot equipment exists**	**600 days**
19	Products developed and launced	30 mons
20	Transition Complete	0 days



Based on the above, the lead time for conversion at Cadila Healthcare Ltd will be about 24 to 26 months from the date of approval of the project. It will be essential to ensure that appropriate quantities of CFCs are made available, in line with the managed requirements during transition.

ATTACHMENT-2

SUMMARY: CIPLA LTD.

1. BASIC DATA AT A GLANCE

Local Ownership: 100%
Exports to Non-Article 5 Countries: 5.60% (2007)
Establishment of Production Line: 1995 (2), 2002 (2), 2003 (3)
Co-financing Commitment: Minimum 30% (presently calculated 59.90%)

2. CFC CONSUMPTION

Parameter	CFC-based MDI Manufacturing Baseline Year: 2003
CFC Consumed (in ODP Tonnes)	526.60

3. PROJECT COST SUMMARY

The table below shows the summary of the elements of the project and the proposed co-financing, at CIPLA Ltd (all amounts in US dollars)

Cost Head	Eligible Costs	Proposed Co-Financing	Proposed Project Funding
Incremental Development Costs	37,890,000	70%	11,367,000
Incremental Capital Costs	11,175,600	35.5%	7,208,262
Incremental Operating Costs	4,411,716	35.5%	2,845,557
TOTAL	**53,477,316**	**59.9%**	**21,420,819**

4. PROJECT COSTS

4.1 Product Development Costs

CIPLA have already developed many of their CFC-based MDI products and relaunched them in HFA format. In addition some of the newer MDIs which have been developed by CIPLA have only been launched in an HFA presentation.

In reviewing the extensive listing of CIPLA's products not all of those listed are eligible for consideration. The following will not be eligible or appropriate for consideration.

a) Isoprenaline Sulphate is an older product being phased out in many countries as it is linked to abuse related issues.

b) Beclomethasone Nasal spray is a nasal delivery system which is adequately replaced with an aqueous spray system which CIPLA already manufactures.

c) Products launched significantly after the 2003/2004: Having reviewed data some products were developed and in the latter stages of registration in 2003, although are not recorded as formally launched until 2004.

Further, consideration has been given to how products in multiple strengths are typically developed. Where three or four strengths of a product are commercialized, it is typical to develop only the highest and lowest strength in detail and to only undertake minimal confirmatory activities on the intermediate strengths.

Applying the criteria above, the following products will be developed:

- Salbutamol (1 strength)
- Salbutamol + Beclomethasone (1 strength)
- Sodium Cromoglycate (1 strength)
- Beclomethasone (3 strengths)
- Budesonide (2 strengths)
- Ipratropium (2 strengths)
- Fluticasone (2 strengths)
- Salmeterol (1 strength)
- Formoterol (1 strength)
- Ipratropium + Salbutamol (1 strength)
- Salmeterol + Fluticasone (2 strengths)
- Sodium Cromoglycate (1 strength)
- Budesonide + Formoterol (1 strength)
- Troventol (1 strength)
- Tiotropium (1 strength)
- Tiotropium +Formoterol (1 strength)

Of these, CIPLA on their own initiative have already formulated 15 and currently 3 (some of which are the more problematic) still have to be formulated. The formulations above represent a minimum of 22 individual formulations (high and low strength for multiple strength products), which will need to be developed.

As a result of the extensive development activities already undertaken by CIPLA, they have developed a very good understanding of the costs associated with the development of an HFA MDI. The development cost estimates take in to consideration the following:

- Some products are far more problematic to reformulate than others

- In order to continue to provide the products internationally, CIPLA's development protocols need to be very demanding, so that the data will be acceptable to all potential reviewing health authorities. CIPLA have a global presence and it is necessary to develop all HFA products in a manner fully compliant with the demands of all regulatory bodies around the world. This avoids the need for unnecessary duplication of the development activities for each territory. The impact of this however is a far more intensive and comprehensive development programme than may be required for solely domestic registration.

Total Cipla Incremental Development Cost is estimated as **US$ 37,890,000.**

4.2 Incremental Capital Costs

Detailed description of the baseline equipment and details of conversion and equipment are provided in Annex-7. The summary is tabulated below (all amounts in US dollars):

Item	Cost
Replacement Line A	4,420,000
1,000 Litre mixing vessel	840,600
Modifications	25,000
Replacement Line B including 500 l vessel	2,080,000
Replacement Line C including 500 l vessel	2,080,000
Bulk storage and distribution modifications	1,730,000
Total	**11,175,600**

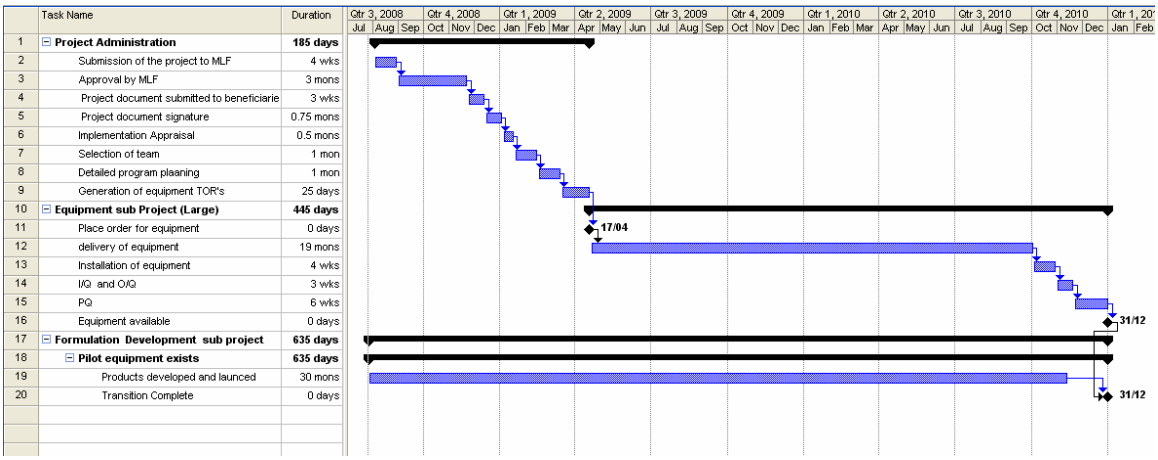
4.3 Incremental Operating costs

Incremental operating costs are calculated based on 2007 production of CFC-based MDIs. The production in 2007 was 27.35 million units. No allowance for future growth in production has been factored. Incremental operating costs are calculated for one year duration.

The incremental operational cost analysis shows that at US$ 0.1613 per unit, the incremental operating costs for one year duration for a production volume of 27.35 million units are calculated at **US$ 4,411,716.**

5. PROJECT SCHEDULE

CIPLA have some equipment suitable for commencing development of HFA MDI formulations, however complete transition to HFA MDIs and hence the elimination of use of CFCs, is dependant on the successful installation of new equipment required as described (in Annex-7) in this proposal. The schedule below takes into account the current equipment procurement lead time in to consideration.



Based on the above, the lead time for conversion at CIPLA Ltd will be about 25 to 27 months from the date of approval of the project. It will be essential to ensure that appropriate quantities of CFCs are made available, in line with the managed requirements during transition.

ATTACHMENT-3

SUMMARY: GLAXOSMITHKLINE PHARMACEUTICALS LTD.

1. BASIC DATA AT A GLANCE

Local Ownership: 49.33%
Exports to Non-Article 5 Countries: 0%
Establishment of Production Line: 1989
Co-financing Commitment: Minimum 30% (presently calculated 81%)

2. CFC CONSUMPTION

Parameter	CFC-based MDI Manufacturing
	Baseline Year: 2003
CFC Consumed (in ODP Tonnes)	24.60

3. PROJECT COST SUMMARY

The table below shows the summary of the elements of the project and the proposed co-financing, at GlaxoSmithKline Pharmaceuticals Ltd (all amounts in US dollars)

Cost Head	Eligible Costs	Proposed Co-Financing	Proposed Project Funding
Incremental Development Costs	0	100%	0
Incremental Capital Costs	1,178,600	81%	223,934
Incremental Operating Costs	330,680	81%	62,829
TOTAL	**1,509,280**	**81%**	**286,763**

4. PROJECT COSTS

4.1 Product Development Costs

GSK have developed and launched many HFA products internationally. Development of the products required for GSK is completed and would be transferred internally. Therefore this cost will be absorbed within the GSK structure.

The products below were all marketed significantly before 2003.

- Ventorlin Inhaler (Salbutamol)
- Becoride Inhaler (BDP)
- Becoride Forte Inhaler (BDP)

4.2 Incremental Capital Costs

Detailed description of the baseline equipment and proposed equipment for conversion can be found in Annex 7. The summary is tabulated below (all amounts in US dollars):

Item	Cost
1 Single Macromat filling line and associated pressure filling and preparation vessel	1,148,600
Modifications to existing area	30,000
Total	**1,178,600**

4.3 Incremental Operating costs

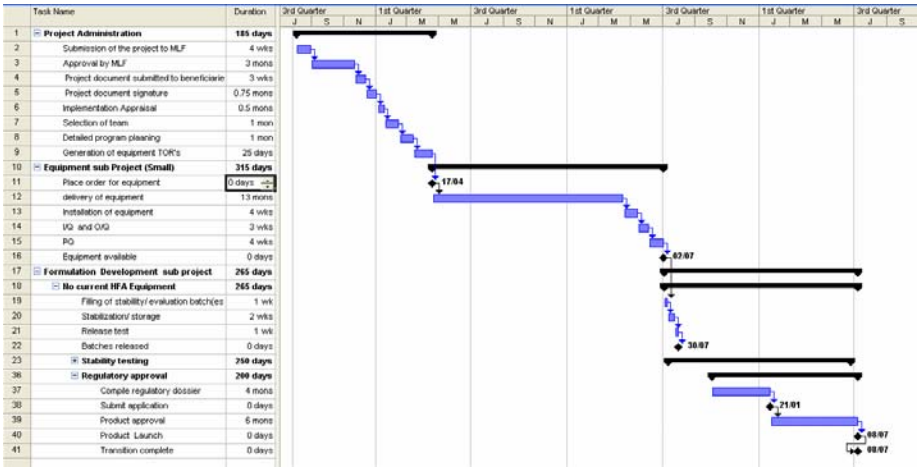
Incremental operating costs are calculated based on 2007 production of CFC-based MDIs. The production in 2007 was 944,801 million units (Ventorlin). No allowance for future growth in production has been factored. Incremental operating costs are calculated for one year duration.

GSK in India will potentially begin manufacture of HFA products as marketed by the international parent company. These are suspension formulations containing no surfactant. As a result they employ packaging components (metering valves and fluoropolymer-coated cans). These are considerably more expensive than the components currently used for the CFC MDI. Based on current costing the additional cost will be about US$ 0.35/unit CFC MDI.

Thus, at US$ 0.35 per unit, the incremental operating costs for one year duration for a production volume of 944,801 units are calculated at **US$ 330,680.**

5. PROJECT SCHEDULE

GSK currently have no equipment suitable to commence development of HFA MDI formulations, therefore complete transition to HFA MDIs and hence the elimination of use of CFCs is dependent on the successful installation and qualification of the equipment referenced in Annex-7 in this proposal. The schedule below takes into account the current equipment procurement lead time in to consideration:



Based on he above, the lead time for conversion at GSK will be about 30 to 32 months from the date of approval of the project. It will be essential to ensure that appropriate quantities of CFCs are made available, in line with the managed requirements during transition.

ATTACHMENT-4

SUMMARY: MIDAS-CARE PHARMACEUTICALS P. LTD.

1. BASIC DATA AT A GLANCE

Local Ownership: 100%
Exports to Non-Article 5 Countries: 0.00
Establishment of Production Line: 1993-1994
Co-financing Commitment: 30%

2. CFC CONSUMPTION

Parameter	CFC-based MDI Manufacturing
	Baseline Year: 2003
CFC Consumed (in ODP Tonnes)	18.78

3. PROJECT COST SUMMARY

The table below shows the summary of the elements of the project and the proposed co-financing, at Midas-Care Pharmaceuticals P. Ltd (all amounts in US dollars)

Cost Head	Eligible Costs	Proposed Co-Financing	Proposed Project Funding
Incremental Development Costs	765,000	30%	535,500
Incremental Capital Costs	780,000	30%	546,000
Incremental Operating Costs	308,850	30%	216,195
TOTAL	**1,853,850**	**30%**	**1,297,695**

4. PROJECT COSTS

4.1 Product Development Costs

In reviewing the extensive listing of products of Midas-Care Pharmaceuticals P. Ltd, not all of those listed are eligible for consideration. The following will not be eligible or appropriate for consideration.

a) Products which Midas-Care have decided they do not intend to make available as an HFA MDI and will be discontinued with the phase out of CFC

b) Products launched significantly after the 2003 baseline year. Having reviewed data, some products were under development and in the latter stages of registration in 2003, although are not recorded as formally launched until 2004. These products do represent eligible formulations/ products as significant volumes were manufactured prior to the baseline.

Further, consideration has been given to how products in multiple strengths are typically developed. Where three or four strengths of a product are commercialized, it is typical to develop only the highest and lowest strength in detail and to only undertake minimal confirmatory activities on the intermediate strengths.

Applying the criteria above, out of the 42 formulations produced by Midas-Care, only 17 formulations are included in the calculation of costs:

a) Salbutamol (1 strength)
b) Ipratropium Bromide (1 strength)
c) Salbutamol +Beclomethasone Dipropionate (1 strength)
d) Formeterol Fumarate (1 strength)
e) Budesonide + Formoterol Fumurate (2 strengths)
f) Beclomethasone Dipropionate (2 strengths)
g) Budesonide (2 strengths)
h) Fluticasone Propionate + Salmeterol (2 strengths)
i) Salbutamol + Ipratropium Bromide (1 strength)
j) Sodium Cromoglycate (1 strength)
k) Tiotropium Bromide (1 strength)
l) Fluticasone Propionate (2 strengths)

Total Midas Care Incremental Development Cost is estimated as **US$ 765,000**

4.2 Incremental Capital Costs

The costs below only cover one CFC MDI line. Detailed description of the baseline equipment and proposed equipment for conversion can be found in Annex 7. The summary is tabulated below (all amounts in US dollars):

Item	Cost
1.5 line manual filling installation	380,000
Pressure filling and preparation vessel	360,000
Custom fabricated table	20,000
Modifications to existing area	20,000
Total	**1,218,000**

4.3 Incremental Operating costs

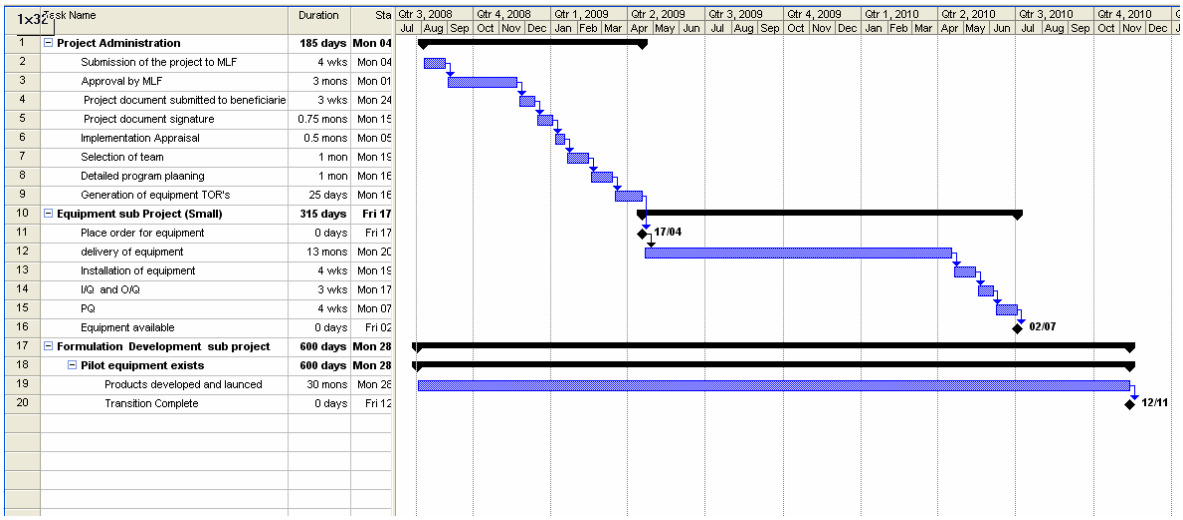
Incremental operating costs are calculated based on 2007 production of CFC-based MDIs. The production in 2007 was 713,387 units. No allowance for future growth in production has been factored. Incremental operating costs are calculated for one year duration.

Midas-Care provided a detailed cost analysis of the anticipated differences between equivalent CFC and HFA MDIs. The detailed analysis can be found in Annex-7. The result of this analysis the incremental cost difference between an equivalent CFC and HFA MDI is approximately Indian Rupees 7.37. This is equivalent to US$ 0.175/unit of CFC-based MDI.

Based on the above, the incremental operating costs at Midas-Care for 1,764,857 units work out to **US$ 308,850.**

5. PROJECT SCHEDULE

Midas-Care have some equipment suitable for commencing development of HFA MDI formulations, however complete transition to HFA MDIs and hence the elimination of use of CFCs, is dependant on the successful installation of new equipment required as described (in Annex-7) in this proposal. The schedule below takes into account the current equipment procurement lead time in to consideration:



a

Based on the above, the lead time for conversion at Midas-Care will be about 22 to 25 months from the date of approval of the project. It will be essential to ensure that appropriate quantities of CFCs are made available, in line with the managed requirements during transition.

ATTACHMENT-5

SUMMARY: SUN PHARMACEUTICAL INDUSTRIES LTD.

1. BASIC DATA AT A GLANCE

Local Ownership: 100%
Exports to Non-Article 5 Countries: 0.00
Establishment of Production Line: 1999-2000
Co-financing Commitment: 30%

2. CFC CONSUMPTION

Parameter	CFC-based MDI Manufacturing
	Baseline Year: 2003
CFC Consumed (in ODP Tonnes)	5.99

3. PROJECT COST SUMMARY

The table below shows the summary of the elements of the project and the proposed co-financing, at Sun Pharmaceutical Industries Ltd. (all amounts in US dollars)

Cost Head	Eligible Costs	Proposed Co-Financing	Proposed Project Funding
Incremental Development Costs	660,490	30%	462,343
Incremental Capital Costs	780,000	30%	546,000
Incremental Operating Costs	67,811	30%	47,468
TOTAL	**1,508,301**	**30%**	**1,055,811**

4. PROJECT COSTS

4.1 Product Development Costs

In reviewing the extensive listing of Sun Pharma's products, not all of those listed are eligible for consideration. The following will not be eligible or appropriate for consideration.

a) Products which Sun Pharma have decided they do not intend to make available as an HFA MDI and will be discontinued with the phase out of CFCs

b) Products launched significantly after the 2003 baseline year. Having reviewed data, some products were under development and in the latter stages of registration in 2003, although are not recorded as formally launched until 2004. These products do represent eligible formulations/ products as significant volumes were manufactured prior to the baseline.

Further, consideration has been given to how products in multiple strengths are typically developed. Where three or four strengths of a product are commercialized, it is typical to develop only the highest and lowest strength in detail and to only undertake minimal confirmatory activities on the intermediate strengths. Applying these criteria, only 10 formulations are included in the calculation of development costs, shown in the table below:

- Salbutamol (1 strength)
- Fluticasone (2 strengths)
- Salmeterol and Fluticasone Propionate (2 strengths)
- Budenoside (2 strengths)
- Formoterol and Budenoside (2 strengths)
- Triptropium (1 strength)

Total Sun Pharma incremental development cost is estimated as **US$ 660,490**

4.2 Incremental Capital Costs

Detailed description of the baseline equipment and proposed equipment for conversion can be found in Annex 7. The summary is tabulated below (all amounts in US dollars):

Item	Cost
1.5 line manual filling installation	380,000
Pressure filling and preparation vessel	360,000
Custom fabricated Table	20,000
Modifications to existing area	20,000
TOTAL	**780,000**

4.3 Incremental Operating costs

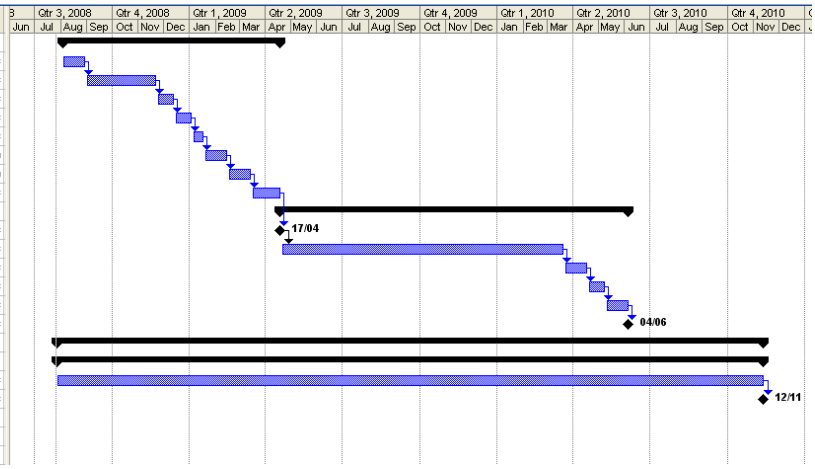
Incremental operating costs are calculated based on 2007 production of CFC-based MDIs. The production in 2007 was 387,492 units. No allowance for future growth in production has been factored. Incremental operating costs are calculated for one year duration.

Sun Pharma could not provide a detailed analysis for differences in costs between equivalent CFC and HFA-based MDIs, as they have only limited exposure HFA-based MDIs. In reviewing the cost quotations provided to Sun Pharma, it is evident that costs and overheads are similar to other enterprises within the sector. It is reasonable therefore to assume that resulting cost differences will also be similar. Therefore, based on a weighted average calculation, the incremental cost difference between an equivalent CFC and HFA MDI is approximately Indian Rupees 7.37. This is equivalent to US$ 0.175/unit of CFC-based MDI. Based on the above, the incremental operating costs at Sun Pharma are **US$ 67,811.**

5. PROJECT SCHEDULE

Sun Pharma currently has no equipment suitable to commence development of HFA MDI formulations, therefore complete transition to HFA MDIs and hence the elimination of use of CFCs is dependent on the successful installation and qualification of the equipment referenced in Annex-7 in this proposal. The schedule below takes into account the current equipment procurement lead time in to consideration:

	Task Name	Duration
1	**Project Administration**	**185 days**
2	Submission of the project to MLF	4 wks
3	Approval by MLF	3 mons
4	Project document submitted to beneficiarie	3 wks
5	Project document signature	0.75 mons
6	Implementation Appraisal	0.5 mons
7	Selection of team	1 mon
8	Detailed program planing	1 mon
9	Generation of equipment TOR's	25 days
10	**Equipment sub Project (Small)**	**295 days**
11	Place order for equipment	0 days
12	delivery of equipment	12 mons
13	Installation of equipment	4 wks
14	I/Q and O/Q	3 wks
15	PQ	4 wks
16	Equipment available	0 days
17	**Formulation Development sub project**	**600 days**
18	**Pilot equipment exists**	**600 days**
19	Products developed and launced	30 mons
20	Transition Complete	0 days



Based on the above, the lead time for conversion at Sun Pharma will be about 24 to 26 months from the date of approval of the project. It will be essential to ensure that appropriate quantities of CFCs are made available, in line with the managed requirements during transition.

ANNEX-2

PROJECT COMPONENT –II: TECHNICAL ASSISTANCE

ANNEX-2

PROJECT COMPONENT-II: TECHNICAL ASSISTANCE

Title:	Technical assistance for implementation of the national strategy for transition to non-CFC MDIs
Implementing Agency:	UNDP
National Coordinating Agency:	Ozone Cell, Ministry of Environment and Forests
Requested Funding:	US$ 350,000
Implementation Timeframe:	January 2009 to December 2012
Impact:	Smooth transition to non-CFC MDIs

Proposed Activities

Technical assistance is proposed to be provided through international experts and, when available, national experts to ensure a smooth transition to the new replacement technology. The experts would need to be process specialists and their functions will include overall technical supervision of conversion projects and technical coordination between equipment/chemical suppliers, beneficiary enterprises and the implementing agency. Their specific responsibilities include:

- Technical assistance for preparing specifications of equipment to be procured in the sub-project
- Technical equipment bid evaluation from suppliers during the competitive bidding process
- Technical guidance to the beneficiary enterprises during start-up with the new equipment and process
- Resolving technical issues with the phase-in of the new equipment and processes
- Technical evaluation of the results of production and product quality trials jointly with the recipient enterprise
- Technical project commissioning including final technical inspection of equipment and process for establishing completion and compliance with project objectives such as the destruction of the baseline CFC-based equipment where applicable, verification of depletion of CFC stocks, and verifying that the non-CFC production process is in operation
- Technical evaluation of enterprise reimbursement claims on equipment, raw materials, local works and other items and certification of the same
- Technical clearance of project completion, so that the project assets can be handed over and the project closed.
- Technical assistance for completion and other reporting requirements.

Budget

Input	Cost (US$)
International Expert(s) Avg. 15 workdays/enterprise X 5 enterprises/year = 300 workdays over 4 years Total 300 workdays @ US$ 600/workday	180,000
National Expert(s) Avg. 15 workdays/enterprise X 5 enterprises = 300 workdays over 4 years Total 300 workdays @ US$ 200/workday	60,000
Expenses (travel, office and miscellaneous reimbursed expenses) over 4 years	110,000
Total:	**350,000**

ANNEX-3

PROJECT COMPONENT –III: SUPPORT FOR POLICY AND REGULATIONS

ANNEX-3

PROJECT COMPONENT-III: SUPPORT FOR POLICY & REGULATIONS

Title:	Support for policy and regulations
Implementing Agency:	UNDP
National Coordinating Agency:	Ozone Cell, Ministry of Environment and Forests
Requested Funding:	US$ 70,000
Implementation Timeframe:	July 2009 to December 2011
Impact:	Revisions to existing regulations for supporting the strategy for sustainable transition to non-CFC MDIs are notified

Proposed Activities

In order to effectively support the transition to non-CFC MDIs, Government of India proposes to consider the following policy and regulatory interventions:

Control of supply of CFC-based MDIs

- Partial licensing of CFC-based MDI manufacturing beyond 2009
- Ban on licensing of any new formulations or products with CFC-based MDIs.
- Ban on import of new CFC-based MDIs. The timing of this measure needs to be aligned with the timing of phase-out of CFCs in MDI manufacturing.

Promotion of CFC-free alternatives

- Fiscal incentives for adopting non-CFC alternatives
- Fast track procedures for approval of non-CFC MDIs

Appropriate amendments to the Ozone Depleting Substances (Regulation and Control) Rules 2000 may also need to be carried out, to align them with the requirements of the national strategy for transition to non-CFC MDIs.

The key stakeholders would be the Ozone Cell, Ministry of Environment & Forests, regulatory authorities from the Ministry of Health & Family Welfare, Ministry of Law, healthcare association and pharmaceutical industry.

The process/steps of implementing these measures would be as below:

- Desk review of existing regulations
- Interaction with stakeholders
- Draft regulations
- Review and consultation meetings of stakeholders
- Finalization and notification

It is expected that the entire process of revising regulations would take approximately 30 months.

Budget

Input	Cost (US$)
Legal advisor (about 120 workdays over 30 months @ US$ 200/workday	24,000
Stakeholder consultation meetings (5 meetings X US$ 5,000 per meeting)	25,000
National seminar on Policy and Regulations (1 seminar X US$ 15,000)	15,000
Documentation, finalization and notification	6,000
Total:	**70,000**

ANNEX-4

PROJECT COMPONENT –IV: SUPPORT FOR AWARENESS AND CAPACITY BUILDING

ANNEX-4

PROJECT COMPONENT-IV: SUPPORT FOR AWARENESS AND CAPACITY-BUILDING

Title:	Support for awareness and capacity building
Implementing Agency:	UNEP
National Coordinating Agency:	Ozone Cell, Ministry of Environment and Forests
Requested Funding:	US$ 350,000
Implementation Timeframe:	July 2009 to July 2012
Impact:	Expedited adoption of non-CFC MDIs for treatment of asthma, COPD and other respiratory ailments

Need Assessment

Awareness and capacity-building actions are considered important and complementary to other initiatives to facilitate quicker adoption of HFA-based MDIs as a reliable treatment for asthma, COPD and other respiratory ailments. Two critical factors would influence quicker market adoption of HFC-based MDIs:

- Prescription of HFC-based MDIs by doctors
- Wide availability of HFC-based MDIs in pharmacies

It is therefore considered necessary to sensitize and engage with stakeholders on the imminent transition to non-CFC MDIs in India, provide adequate information dissemination and training and ensure that non-CFC MDIs are regularly prescribed and widely available.

Stakeholders

Government: Ministry of Environment & Forests, Ministry of Health & Family Welfare and related regulatory authorities such as CDSCO and DCGI and including the Pharmacy Council of India, which regulates Pharmacy education in India.

Research Institutions: Indian Council of Medical Research, one of the oldest medical research bodies in the world, functions as an apex research and advisory body to Government for control and management of diseases.

Educational Institutions: The Vallabhbhai Patel Chest Institute in Delhi is a unique and preeminent medical institution dedicated to study and treatment of chest diseases, funded entirely by the Ministry of health and Family Welfare.

Medical Associations: The Indian Medical Association (IMA) is the only representative voluntary association of medical practitioners of modern medicine and has a membership of about 100,000 doctors with over 1,200 branches spread nationwide

Industry Associations: The Indian Pharmaceutical Association is the premier association of pharmacists in India, engaged in continuing education and training, good practices, and updating knowledge on technology, research and regulations.

The Indian Drug Manufacturers Association (IDMA) is the premier representative association of the pharmaceutical manufacturers in India.

Other Organizations: Such as the Indian Chest Society and National College of Chest Physicians are dedicated to disseminating knowledge and conducting training programs on management of Asthma and COPD.

Proposed Activities

The proposed activities for promoting awareness of the imminent transition to non-CFC MDIs would comprise of the following:

- Information dissemination and awareness through seminars and workshops
- Development and distribution of promotional materials
- Promoting public awareness

The activities would require an active engagement of all stakeholders described above for maximum effectiveness and outreach.

Budget

Input	Cost (US$)
Regional workshops for medical practitioners (5 X US$10,000)	50,000
Regional workshops for pharmacists (5 X 10,000)	50,000
Training and information materials on non-CFC MDIs and transition	50,000
Public awareness materials including advertisements	150,000
Sub-contract for design and development of awareness materials	50,000
Total:	**350,000**

ANNEX-5

PROJECT COMPONENT –V: SUPPORT FOR MANAGEMENT AND MONITORING

ANNEX-5

PROJECT COMPONENT-V: SUPPORT FOR MANAGEMENT AND MONITORING

Title:	Support for management and monitoring
Implementing Agency:	UNDP
National Coordinating Agency:	Ozone Cell, Ministry of Environment and Forests
Requested Funding:	US$ 400,000
Implementation Timeframe:	January 2009 to December 2012
Impact:	Timely project implementation, monitoring and reporting

Need Assessment

The implementation of the national strategy for transition to non-CFC MDIs will need to be closely aligned and coordinated with the various policy, regulatory, awareness and capacity-building actions the Government of India is taking and will need to take in future, in order to ensure that the implementation of the strategy is consistent with the Country Programme principles and with the National Health Policy. Further, in view of the time-bound targets needed to be achieved the implementation of the Plan will need to be closely and efficiently managed and will introduce additional coordinating, reporting and monitoring activities.

Proposed Activities

The implementation of the strategy will be managed by a dedicated management team, comprising of a coordinator to be designated by the Ozone Cell and supported by representatives and experts from the implementing/executing agencies and the necessary support infrastructure. The management component of the strategy will include the following activities, for the duration of the Plan:

- Establishment and operation of the management unit
- Coordination of the implementation of various components of the strategy, with the required Government policy and regulatory actions
- Progress/status reporting including management of databases
- Coordination of enterprise-level implementation and phase-out activities
- Establishment and operation of a decentralized mechanism for monitoring and evaluation of Plan outputs, in association with the relevant regulatory bodies
- Verification and certification of CFC phase-out at the enterprise level

Budget

Input	Cost (US$)
Personnel costs including two support staff (4 years)	200,000
Infrastructure costs	20,000
Operational costs	100,000
Independent verification and reporting (US$ 15,000/year for 4 years)	80,000
Total:	**400,000**

ANNEX-6

LETTERS OF COMMITMENT FROM BENEFICIARY ENTERPRISES

Zydus
dedicated to life

Cadila
Healthcare Limited

Sarkhej-Bavla N. H. No. 8A,
Moraiya. Tal. : Sanand,
Dist. : Ahmedabad 382 210. India.
Phone : +91-2717-250331/32/36/37
Fax : +91-2717-250319
www.zyduscadila.com

LETTER OF COMMITMENT

I, Shirsh G. Belapure – President Manufacturing , on behalf of *Cadila Healthcare Limited, Ahmedabad, India* do hereby declare and affirm as below:

THAT we have read and reviewed the project proposal prepared by UNDP, for conversion of our CFC-based MDI manufacturing facilities to non-CFC-based technology at *Cadila Healthcare Limited Ahmedabad, India*;

THAT we have been briefed on and understood the various rules and criteria of the Multilateral Fund for the Implementation of the Montreal Protocol, governing costs, technology, eligibility, funding and counterpart financing;

THAT we are in agreement with the proposed technology conversions, the estimated costs, the proposed funding levels and implementation schedules;

THAT we undertake to implement the conversion to non-CFC-based MDI products and to phase-out the use of CFCs in manufacturing MDIs in accordance with the transition schedule as proposed and also undertake not to revert to use of CFCs in future in any of our MDI manufacturing facilities;

THAT we understand that the proposal will be submitted to the next meeting of the Executive Committee of the Multilateral Fund for its consideration, that the proposal may be subject to funding negotiations between the Executive Committee and Government of India and the net funding that would be actually provided could be lesser than that indicated in the proposal;

THAT we agree to abide by the rules and regulations that may be promulgated by Government of India in context of this project and in context of MDIs in India;

THAT we would abide by the UNDP and Government of India rules and regulations pertaining to finance/accounting, procurement, project management, monitoring and reporting during the implementation stage of the project.

Place: Ahmedabad
Date: 29/07/2008

For and on behalf of *Cadila Healthcare Limited*

Shirsh G. Belapure – President Manufacturing
Authorized Signatory

Cipla

Cipla Ltd.
C-1 Pooja Apts, 17 Hariyali Estate,
Vikhroli (West), Mumbai 400 083.
Tel. : (91-22) 25786604, 25786605,
25784195, 25783843
Fax : (91-22) 25795025

LETTER OF COMMITMENT

I, **R.M. Nikam, Director Supply Chain**, on behalf of **Cipla Ltd, Mumbai (India)**, do hereby declare and affirm as below:

THAT we have been briefed on and understood the various rules and criteria of the Multilateral Fund for the Implementation of the Montreal Protocol, governing costs, technology, eligibility, funding and counterpart financing;

THAT we are in agreement with the proposed technology conversions, the estimated costs, the proposed funding levels and implementation schedules;

THAT we undertake to implement the conversion to non-CFC-based MDI products and to phase–out the use of CFCs in manufacturing MDIs.

THAT we hereby, commit to phase-out the usage of CFC in MDIs by December, 2012. However, till then, the quantities which have been projected year-wise as contained in our project report will be used.

NOTWITHSTANDING what is stated in above paragraphs, we will do our best to phase-out CFC at the earliest possible.

THAT we understand that the proposal will be submitted to the next meeting of the Executive Committee of the Multilateral Fund for its consideration, that the proposal may be subject to funding negotiations between the Executive Committee and Government of India and the net funding that would be actually provided could be lesser than that indicated in the proposal;

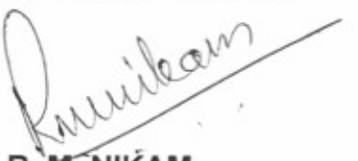
THAT we agree to abide by the rules and regulations that may be promulgated by Government of India in context of this project and in context of MDIs in India;

THAT we would abide by the UNDP and Government of India rules and regulations pertaining to finance/accounting, procurement, project management, monitoring and reporting during the implementation stage of the project.

Place: Mumbai

Date: 12.08.2008

For and on behalf of **CIPLA LIMITED**



R M NIKAM
DIRECTOR – SUPPLY CHAIN

GlaxoSmithKline

GlaxoSmithKline
Pharmaceuticals Limited
A - 10, M.I.D.C.
Ambad-Pathardi Block,
Nashik-422 010. INDIA.

Tel. : 0253-2300346 / 2300404
Fax : 0253 - 2381274

LETTER OF COMMITMENT

I, ***Bhanwar Singh Yadav, Vice President, Nashik factory***, on behalf of ***M/s GlaxoSmithkline Pharmaceuticals Ltd.,*** do hereby declare and affirm as below:

THAT we have read and reviewed the project proposal prepared by UNDP, for conversion of our CFC-based MDI manufacturing facilities to non-CFC-based technology at ***GlaxoSmithkline Pharmaceuticals Ltd. ;***

THAT we have been briefed on and understood the various rules and criteria of the Multilateral Fund for the Implementation of the Montreal Protocol, governing costs, technology, eligibility, funding and counterpart financing;

THAT we are in agreement with the proposed technology conversions, the estimated costs, the proposed funding levels and implementation schedules;

THAT we undertake to implement the conversion to non-CFC-based MDI products wherever applicable and to phase-out the use of CFCs in manufacturing MDIs in accordance with the transition schedule as proposed and also undertake not to revert to use of CFCs in future in any of our MDI manufacturing facilities;

THAT we understand that the proposal will be submitted to the next meeting of the Executive Committee of the Multilateral Fund for its consideration, that the proposal may be subject to funding negotiations between the Executive Committee and Government of India and the net funding that would be actually provided could be lesser than that indicated in the proposal;

THAT we agree to abide by the rules and regulations that may be promulgated by Government of India in context of this project and in context of MDIs in India;

THAT we would abide by the UNDP and Government of India rules and regulations pertaining to finance/accounting, procurement, project management, monitoring and reporting during the implementation stage of the project.

Place: Nashik
Date: 7th August 2008

For and on behalf of GlaxoSmithkline Pharmaceuticals Ltd.

Bhanwar Singh Yadav
Vice President, Nashik factory
Authorized Signatory

Regd. Office
Dr. Annie Besant Road,
Worli, Mumbai - 400 030. INDIA.

भारत सरकार
पर्यावरण एवं वन मंत्रालय
ओज़ोन सेल
Government of India
Ministry of Environment and Forests
Ozone Cell

सत्यमेव जयते

DR. A. DURAISAMY
Director, Ozone Cell

D. O. No. 38/1/2008-OC

Dated : 1st October, 2008

Dear Mr. Chirmulay,

This is to acknowledge receipt of India's proposal for the National Strategy for Transition to non-CFC MDIs and Plan for phase-out of CFCs in pharmaceutical MDIs in India. The document was reviewed by us and subject to our comments as indicated in our message dated 25th September 2008, our concurrence to the contents is confirmed. I hereby request UNDP for its assistance in submission of this proposal to the 56th meeting of the Executive Committee.

With Kind regards,

Yours sincerely,

(A. DURAISAMY)

Mr. Nandan Chirmulay
Regional Coordinator
Montreal Protocol/Chemicals Unit
Environment and Energy Group
UNDP-Thailand
Regional Center in Bangkok, UN Services
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web : ozonecell.com

Midas-Care
We Care

MIDAS-Care
PHARMACEUTICALS PVT LTD
Papa Industrial Estate, 40 Suren Road
Andheri (East), Mumbai 400 093
Tel : 2683 5678, 2683 3409
Fax : 91 22 2683 7947
E-mail : aerosol@vsnl.com

LETTER OF COMMITMENT

I, **Ms Sangithaa Gupta**, **Managing Director**, on behalf of **Midas-Care Pharmaceuticals Pvt. Ltd.** do hereby declare and affirm as below:

THAT we have read and reviewed the project proposal prepared by UNDP, for conversion of our CFC-based MDI manufacturing facilities to non-CFC-based technology at **Midas-Care Pharmaceuticals Pvt.Ltd. ;**

THAT we have been briefed on and understood the various rules and criteria of the Multilateral Fund for the Implementation of the Montreal Protocol, governing costs, technology, eligibility, funding and counterpart financing;

THAT we are in agreement with the proposed technology conversions, the estimated costs, the proposed funding levels and implementation schedules;

THAT we undertake to implement the conversion to non-CFC-based MDI products and to phase-out the use of CFCs in manufacturing MDIs in accordance with the transition schedule as proposed and also undertake not to revert to use of CFCs in future in any of our MDI manufacturing facilities;

THAT we understand that the proposal will be submitted to the next meeting of the Executive Committee of the Multilateral Fund for its consideration, that the proposal may be subject to funding negotiations between the Executive Committee and Government of India and the net funding that would be actually provided could be lesser than that indicated in the proposal;

THAT we agree to abide by the rules and regulations that may be promulgated by Government of India in context of this project and in context of MDIs in India;

THAT we would abide by the UNDP and Government of India rules and regulations pertaining to finance/accounting, procurement, project management, monitoring and reporting during the implementation stage of the project.

Place: Mumbai
Date: July 26, 2008

For and on behalf of Midas-Care Pharmaceuticals Pvt Ltd.

Sangithaa

Ms Sangithaa Gupta, Managing Director
Authorized Signatory

MIDAS CARE PHARMACEUTICALS PVT. LTD. MUMBAI

Factory : B - 16, MIDC, Waluj, Aurangabad 431 136 Tel: 91 0240 255 4739 Fax : 91 0240 255 5408 E-mail : midas_care@vsnl.com

17-B, Mahal Industrial Estate,
Mahakali Caves Road, Andheri (E),
Mumbai - 400 093. India.
Tel. : (91-22) 6645 5645
Fax : (91-22) 6645 5685

SUN PHARMACEUTICAL INDUSTRIES LTD.

LETTER OF COMMITMENT

I, Mr. Kirti Ganorkar, Vice President (Business Development) , on behalf of Sun Pharmaceutical Industries Limited do hereby declare and affirm as below:

THAT we have read and reviewed the project proposal prepared by UNDP, for conversion of our CFC-based MDI manufacturing facilities to non-CFC-based technology at Sun Pharmaceutical Industries Limited

THAT we have been briefed on and understood the various rules and criteria of the Multilateral Fund for the Implementation of the Montreal Protocol, governing costs, technology, eligibility, funding and counterpart financing;

THAT we are in agreement with the proposed technology conversions, the estimated costs, the proposed funding levels and implementation schedules;

THAT we undertake to implement the conversion to non-CFC-based MDI products and to phase-out the use of CFCs in manufacturing MDIs in accordance with the transition schedule as proposed and also undertake not to revert to use of CFCs in future in any of our MDI manufacturing facilities;

THAT we understand that the proposal will be submitted to the next meeting of the Executive Committee of the Multilateral Fund for its consideration, that the proposal may be subject to funding negotiations between the Executive Committee and Government of India and the net funding that would be actually provided could be lesser than that indicated in the proposal;

THAT we agree to abide by the rules and regulations that may be promulgated by Government of India in context of this project and in context of MDIs in India;

THAT we would abide by the UNDP and Government of India rules and regulations pertaining to finance/accounting, procurement, project management, monitoring and reporting during the implementation stage of the project.

Place: Mumbai
Date: 29th July, 2008

For and on behalf of Sun Pharmaceutical Industries Ltd.,

Kirti Ganorkar
(Vice President -Business Development)