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Distr.
GENERAL

UNEP/OzL.Pro/ExCom/52/22
22 June 2007

CHINESE
ORIGINAL: ENGLISH

执行蒙特利尔议定书
多边基金执行委员会
第五十二次会议
2007 年 7 月 23 日至 27 日，蒙特利尔

开发计划署 2007 年工作方案的修正

基金秘书处的评论和建议

1. 开发计划署请执行委员会为其 2007 年工作方案修正案核准 813,345 美元，外加 56,745 美元的机构支助费用。

2. 开发计划署工作方案修正案拟议的活动如下文表 1 所示：

表 1：开发计划署的工作方案修正案

国家	活动/项目	所需数额（美元）	建议数额（美元）
A 节：建议一揽子核准的活动			
A.1 延长体制建设			
巴西	体制建设：第五阶段	351,000	351,000
哥伦比亚	体制建设：第六阶段	275,600	275,600
	一揽子核准小计：	626,600	626,600
B 节：建议个别审议的活动			
B.1 项目编制			
哥伦比亚	计量吸入器投资项目的项目编制	30,000	供个别审议
印度	计量吸入器投资项目的项目编制	100,000	供个别审议
	个别审议小计：	130,000	
A 节和 B 节小计：		756,600	
机构支助费用（7.5%用于项目编制和体制建设以及超过 250,000 美元的其他项目，9%用于其他 250,000 美元以下的项目）：		56,745	46,995
共计：		813,345	673,595

A 节：建议一揽子核准的活动

A.1 延长体制建设

巴西：体制建设：（第五阶段）： 351,000 美元

哥伦比亚：体制建设：（第六阶段）： 275,600 美元

项目说明

3. 开发计划署为巴西和哥伦比亚提交了延长体制建设项目的申请。这两个国家的体制建设项目说明载于本文件附件一。

基金秘书处的评论和建议

4. 基金秘书处建议按照表 1 所示供资数额一揽子核准巴西和哥伦比亚延长体制建设的申请。谨建议执行委员会向巴西政府和哥伦比亚政府表达本文件附件二所载的评论。

B 节：建议个别审议的活动

B.1 项目编制

氟氯化碳计量吸入器转换项目的项目编制：哥伦比亚和印度

背景

5. 在其第五十一次会议上，执行委员会在第 51/34 号决定中同意特别“在个案的基础上审议申请编制转换氟氯化碳计量吸入器生产设施的项目的呈件，但有一项谅解，即有关国家应在申请中全面说明需要援助的理由，并作为起码条件应提供下列详细资料：

（a）国家拥有的氟氯化碳计量吸入器生产设施的名称，建立氟氯化碳生产线的日期和每一生产线的生产能力；

（b）生产的氟氯化碳计量吸入器的种类，使用的活性成分，年产量（件/年）；

（c）过去 5 年氟氯化碳计量吸入器的产量增长情况；

（d）氟氯化碳计量吸入器生产工厂有否考虑氟氯化碳计量吸入器的代用品，这种代用品为何；

（e）各生产设施淘汰氟氯化碳消费的计划；以及

（f）不含氟氯化碳的计量吸入器及干粉吸入器在缔约方销售的数量，按其活性成分、商标/厂家和来源分别列出 。”

6. 开发计划署为哥伦比亚和印度提交了关于计量吸入器行业转换项目的项目编制申请。下文概述了开发计划署依照上述决定的要求为每份申请提供的数据。

哥伦比亚：计量吸入器投资项目的项目编制：30,000 美元

项目说明

7. 开发计划署代表哥伦比亚政府，提交了项目编制申请，旨在淘汰计量吸入器制造业的氟氯化碳用途。哥伦比亚国家氟氯化碳淘汰计划[1]报告说，所有氟氯化碳计量吸入器都是进口到该国的，本国没有在当地生产氟氯化碳计量吸入器。那时，政府并没有意识到哥伦比亚有一家氟氯化碳计量吸入器生产商。编制国家氟氯化碳淘汰计划时，哥伦比亚认识到尽管用于计量吸入器的氟氯化碳消费量为零，哥伦比亚政府和卫生当局仍非常关注计量吸入器的次级行业，并请求提供资金，用以制定一项计量吸入器过渡战略，为进口氟氯化碳计量吸入器的替代品设定一个明确的时间表。此外，还需要制定法规宣传和支持淘汰这些产品的工作，并编制方案提高对氟氯化碳计量吸入器替代品的医学认识和耐心接受度。

8. 为了支持它们根据第 51/34 号决定提交文件以获得项目编制资金，开发计划署表示，哥伦比亚政府有一家由本国公民拥有的氟氯化碳计量吸入器制造企业，即 Laboratorios Chalver de Colombia S.A.。该公司成立于 2002 年，只有一条生产线，运作能

[1] 执行委员会在 2003 年的第四十一次会议上核准了该计划（UNEP/OzL.Pro/ExCom/41/29）（第 41/52 号决定）。

力为每小时 2,000 至 3,000 件。

9. 报告还声明，在 2006 年，公司生产了 113,000 件计量吸入器。这些产品中，大约 60%用于国内消费，剩余的 40%用于出口。下表列示了过去三年的年产量。迄今为止，就下表所列组成部分而言，2007 年的产量已达到 61,000 件。

组成部分	年产量（件/年）			
	2003 年	**2004 年**	**2005 年**	**2006 年**
沙丁胺醇	144,000	300,000	-	72,000
沙丁胺醇/异丙托铵	-	-	10,000	5,000
沙丁胺醇/倍氯米松	6,000	3,000	36,000	15,000
倍氯米松	63,000	69,000	3,000	9,000
异丙托铵	-	42,000	78,000	12,000
产量共计	213,000	414,000	127,000	113,000

10. 下表显示出了计量吸入器行业氟氯化碳用途的趋势，与国家方案年度执行报告报告的情况一致：

物质	2003 年	2004 年	2005 年	2006 年
CFC-11	2.52	2.80	0.80	0.56
CFC-12	3.56	5.28	1.00	1.65
共计	6.08	8.08	1.8	2.21

11. 该公司正在考虑将其生产线改进成氢氟烷烃，不过，它们非常关注当前市场上的氢氟烷烃配方。该公司估计需要两到三年的时间才能完成改进过程，同时确保所生产药品的质量相当于当前生产和进口的氟氯化碳计量吸入器。

12. 哥伦比亚主要通过跨国公司进口非氟氯化碳计量吸入器。本文件没有提供关于进口量的数据，尽管它们在有干粉吸入器或氢氟烷烃配方的地方列出了一份活性成分清单。

基金秘书处的评论

13. 提交本项目编制申请是为了能够淘汰生产氟氯化碳计量吸入器时使用的 2.1 ODP 吨的氟氯化碳。审查提交的数据时，秘书处注意到，正如生产的总件数所示，总体而言，2003 至 2006 年的产量呈下降趋势。回复秘书处关于产量下降原因的询问时，开发计划署表示，那是当前市场上从印度进口的便宜氟氯化碳计量吸入器的可获性造成的。

14. 此外，秘书处还希望澄清该公司迟迟不肯在生产过程中转用氢氟烷烃推进剂的原因，情况表明，这样做并没有任何技术限制。开发计划署回复说，为转换成氢氟烷烃而作的变动主要是改进生产线，这其中最主要的，是改变剂量泵和填充头。尚未确定是否需要新设备，这一点取决于编制该项目时选择的配方。

15. 秘书处还请开发计划署依照第 51/34 号决定要求，提供该国非氟氯化碳计量吸入器进口情况的数据。从所提供的列表中，可以看出哥伦比亚进口了非氟氯化碳计量吸入器，用于倍氯米松和沙丁胺醇。在哥伦比亚，这两样产品都是作为氟氯化碳计量吸入器生产和销售的。进口的其他非氟氯化碳计量吸入器都是一些哥伦比亚国内当前不生产的产品。

16. 审查与将转换的公司数量、将实现的氟氯化碳淘汰量及本国非氟氯化碳计量吸入器

可获状况有关的供资申请时，秘书处向开发计划署建议，项目编制工作可以在花费不超过30,000 美元的情况下进行。开发计划署同意秘书处的建议，即为科威特的项目编制提供较低的费用。

基金秘书处的建议

17. 根据上述评论，谨建议执行委员会按照上文表 1 所示 30,000 美元供资水平核准该项目编制申请。此外，还建议委员会确认所提供的信息是否符合第 51/34 号决定的要求。

18. 核准该项目时，应要求开发计划署注意，根据第 51/34 号决定，在编制该投资项目时，最后文件必须包含过渡战略的基本内容，以协助计量吸入器行业，并支持全面实施该投资项目。还应该注意到，关于本行业的单独过渡战略不会获得进一步的供资。

印度：计量吸入器投资项目的项目编制：100,000 美元

项目说明

19. 开发计划署代表印度政府提交了一份关于在印度编制氟氯化碳计量吸入器生产厂家转换项目的申请。在其国家氟氯化碳淘汰计划中，印度报告说，生产计量吸入器消费了120 ODP 吨的氟氯化碳。虽然它们最初表示淘汰计划不会涉及这一消费量，因为其重点是制冷行业，但是，印度现在希望开始转换其氟氯化碳计量吸入器生产设施，以便在开发计划署的协助下淘汰该行业的氟氯化碳用途。截至 2006 年，该行业的氟氯化碳消费量超过了 700 ODP 吨，这种情况为该项申请提供了有力支持。

20. 作为第 51/34 号决定所要求的支持项目编制申请的信息的一部分，开发计划署表示，印度有七家氟氯化碳计量吸入器制造企业，包含 9 个生产厂家。其中一家企业 Cipla 拥有三个生产厂家。

21. 在这七家制造企业当中，有 4 家是完全国有的，1 家国有份额占 70%，另一家占 49.3%，最后一家占 10 %。下表概述了这些企业、其成立日期、国有比例及其生产能力。

公司名称	成立日期	国有比例	生产能力
AstraZeneca Pharma India Ltd.	1981 年 11 月	*自 2006 年起暂借地方进行生产	*自 2006 年起暂借地方进行生产
Cadila Health Care Ltd.	1995 年 5 月	100	一条生产线，产量为 800 万件/年
Cipla Ltd , Kurmumbh, Mh	1993 年 11 月	100	3 个工厂，生产线总产量为 7,000 万件/年
Cipla Kundaim, Goa	1997 年 10 月		
Cipla Verna, Goa	2000 年 1 月		
葛兰素史克制药有限公司	1990 年	49.3	一条生产线，产量为 300 万件/年
Midas Care Pharmaceuticals Pvt. Ltd.	1993 年	100	两条生产线，每条生产线的产量为 750 万件/年
Natco Pharma Ltd.	1981 年	10	一条生产线，产量为 300 万件/年
太阳医药实业公司	2001 年	70	一条生产线，产量为 200 万件/年

22. 如下表所示，开发计划署还提供信息介绍了这些工厂 2005 年的年度生产定额，以及过去三年计量吸入器生产中的氟氯化碳使用情况。

公司名称	年生产定额（2005 年）	用于计量吸入器生产的氟氯化碳的量（长吨）		
		2003 年	2004 年	2005 年
AstraZeneca Pharma India Ltd.	*暂借 Midas 之地生产	3.6	2.3	0.5
Cadila Health Care Ltd.	120 万件	3.0	4.8	7.5
Cipla Ltd (Kurmumbh)	4,200 万件	573.0	688.0	674.0
Cipla (Kundaim, Goa)				
Cipla (Verna, Goa)				
葛兰素史克制药有限公司	80 万件	29.2	24.6	27.6
Midas Care Pharmaceuticals Pvt. Ltd.	200 万件	18.8	21.3	29.8
Natco Pharma Ltd.	10,000 件	3.3	1.1	1.0
太阳医药实业公司	40 万件	8.3	7.2	6.9
共计	约 4,600 万件	639.2	749.3	747.3

23. 报告还表示，这九个生产厂家中，只有五个计划转向非氟氯化碳生产，而且，有一家公司 Astra Zeneca Pharma India Ltd.自 2006 年起转而暂借 Midas Care Pharmaceuticals Pvt. Ltd.之地进行生产。开发计划署简单介绍了那些旨在转向非氟氯化碳生产的计划，估计的转换时期在两年到十年之间。开发计划署表示，印度政府拟协助这七家制造商，因为它们必须获得财政援助以改变其生产非氟氯化碳的能力，进而帮助印度履行其在《蒙特利尔议定书》项下的义务。

24. 印度部进口非氟氯化碳计量吸入器。目前，该国生产氢氟烷烃计量吸入器的企业有两家：Cipla 和 Midas Care。下表概述了这两家企业每年、每种活性成分生产的件数。

公司名称	活性成分（人造）	件数（2005 年）
Cipla - Kundaim, Goa	沙丁胺醇	2,270,000
	布地缩松	8,695,000
	倍氯米松	40,000
	布地缩松+福莫特罗	34,000
	氟替卡松	18,000
Cipla - Verna, Goa	丙酸倍氯米松	615,632
	异丙托溴铵	4,600
	沙丁胺醇	1,226,726

	Salmetrerol Xinafote	1,921
	沙丁胺醇和异丙托溴铵	7,480
	Salmeterol 和氟替卡松丙酸酯	8,137
Midas Care	沙丁胺醇	5,000
	福莫特罗 + 布地缩松	20,000
	Salmetrerol + 氟替卡松	10,000
	共计	约 1,300 万件

基金秘书处的评论

25. 提交本项目编制申请是为了能够淘汰生产氟氯化碳计量吸入器时使用的约 700 ODP 吨的氟氯化碳。开发计划署为印度提供的氟氯化碳用途数据显示，2003 至 2004 年间，消费量有所增加，2007 年，消费量略有下降。文件没有解释消费量下降的原因，不过，与开发计划署的讨论表明，鉴于减少的量极少，那可能是计量吸入器的配方有所改变造成的。

26. 秘书处注意到，在上述七家企业中，那三家全国有的企业也是最大的氟氯化碳计量吸入器制造商。其中两家企业，Cipla 和 Midas Care 同时也是当地的非氟氯化碳计量吸入器制造商。正如提交给执行委员会第五十一次会议的文件 UNEP/OzL.Pro/ExCom/51/39 的第 20（b）段注意到的那样，“印度具有第二大市场份额的制药公司在 2000 年推出了不含氟氯化碳的吸入器。[2] 目前，该公司向几个第 5 条和非第 5 条缔约方销售氟氯化碳和氢氟烷烃计量吸入器。”其他四家企业主要由私人和跨国公司持股，如果费用允许，它们须受母公司转向非氟氯化碳替代品的政策的约束。

27. 秘书处还注意到并与开发计划署讨论了下面这个问题：报告没有提供数据介绍过去五年里以件数计的氟氯化碳计量吸入器产量的增长趋势。秘书处被告知，有一些数据，但印度不愿意提供，主要原因包括：这些信息没有经过实地核查；保密性问题。开发计划署表示，可以以用于计量吸入器生产的氟氯化碳使用量增加为依据，说明印度的氟氯化碳计量吸入器产量呈逐步增长的趋势。

28. 秘书处还注意到，根据上文第 24 段，对计量吸入器的某些活性成分而言，印度已经掌握了氢氟烷烃技术，而且，非氟氯化碳计量吸入器已在当地生产并在市场上销售。它向开发计划署建议，鉴于上述情况，项目编制工作可在供资水平较低（70,000 美元）的情况下完成。

29. 在讨论中，开发计划署表示，考虑到有大量工厂位于国内偏远地区的制造商的数量、繁多的氟氯化碳计量吸入器类型以及更重要的，协助项目编制进程所需国际顾问的有限性和高成本，应建议为项目编制工作核准申请的供资。他们还表示，在编制项目的同时，有必要开展一个广泛的磋商进程，以确保所有的有关利益方都理解这一进程，而且过

[2] 成功引入无氟氯化碳的沙丁胺醇吸入器之后，Cipla 还推出了世界上第一款无氟氯化碳的布地缩松吸入器（资料来源：董事编制的公司第六十四次年度报告和截至 2000 年 3 月 31 日的已审计决算）。

渡工作将会平稳进行。

基金秘书处的建议

30. 根据上述评论，谨建议执行委员会按照上文表 1 所示 100,000 美元的供资水平核准该项目编制申请。此外，还建议委员会确认所提供的信息是否符合第 51/34 号决定的要求。

31. 核准该项目时，应要求开发计划署注意，根据第 51/34 号决定，在编制该投资项目时，最后文件必须包含过渡战略的基本内容，以协助计量吸入器行业，并支持全面实施该投资项目。还应该注意到，关于本行业的单独过渡战略不会获得进一步的供资。

附件一

体制建设项目提案

巴西：延长体制建设

项目摘要和国家概况	
执行机构：	开发计划署
以前核准的体制建设供资数额（美元）： 第一阶段：1993 年 7 月 第二阶段：1998 年 3 月 第三阶段：2000 年 12 月 第四阶段：2004 年 7 月 共计	 403,100 270,000 270,000 351,000 1,294,100
延长所需数额（第五阶段）（美元）：	351,000
第五阶段建议核准数额（美元）：	351,000
机构支助费用（美元）：	26,325
多边基金体制建设第五阶段总成本（美元）：	377,325
由于体制建设第五阶段同等数量氟氯化碳淘汰成本为 12.1 美元/公斤（ODP 吨）：	暂缺
国家方案核准日期：	1994 年 7 月
国家方案报告的 ODS 消费量（1993 年）（ODP 吨）：	10,861.6
最近报告的 ODS 消费量（2005 年）（ODP 吨）：	2,076.9
受控物质基准消费量（ODP 吨）： (a) 附件 A 第一类物质（氟氯化碳）（1995-1997 年平均数） (b) 附件 A 第二类物质（哈龙）（1995-1997 年平均数） (c) 附件 B 第二类物质（四氯化碳）（1998-2000 年平均数） (d) 附件 B 第三类物质（三氯乙酸）（1998-2000 年平均数） (e) 附件 E（甲基溴）（1995-1998 年平均数）	 10,525.8 21.3 411.6 32.4 711.6
受控物质的最近消费量（2005 年）（ODP 吨）： (a) 附件 A 第一类物质（氟氯化碳） (b) 附件 A 第二类物质（哈龙） (c) 附件 B 第二类物质（四氯化碳） (d) 附件 B 第三类物质（三氯乙酸） (e) 附件 E（甲基溴） (f) 附件 C 第一类物质（氟氯烃）	 967.2 3.0 0.0 0.0 259.5 847.2
核准的项目供资数额（美元）：	90,926,718
支付的数额（截至 2007 年 3 月）（美元）：	69,356,952
将淘汰的 ODS（ODP 吨）：	12,441.1
已淘汰的 ODS（截至 2007 年 3 月）（ODP 吨）：	11,116.7

1. 活动摘要及执行委员会核准的供资数额：

活动摘要	**核准的供资数额（美元）**

(a)	投资项目：	85,134,468
(b)	体制建设：	1,443,028
(c)	项目编制、技术援助、培训和其他非投资项目：	4,349,222
	共计：	90,926,718

进度报告

2. 巴西体制建设项目第四阶段期间，国家臭氧机构继续积极工作，以遵守《蒙特利尔议定书》淘汰时间表。为防止全球变暖，巴西政府促进了各种旨在保护臭氧层和提高能效的行动。在该阶段里，还完成了旨在控制消耗臭氧层物质贸易和预防非法贩运的海关官员培训。培训的成果就是没收了一些走私的消耗臭氧层物质。此外，还积极地与私营部门、一些协会如巴西制冷空调通风供热协会（ABRAVA）、电子电器协会（ELETROS）以及农业部门里以装饰性花卉为导向的协会开展定期磋商。完成了提高认识活动，包括翻译了名为“OZZY OZONIO”的录像。这段录像已被以国语分发给了不同的受众，包括巴西航空公司。此外，还编制并向公众分发了关于臭氧消耗对健康的影响的新闻资料。该项目还允许臭氧机构小组参与制冷相关博览会以介绍《蒙特利尔议定书》，并参加公共和私人组织里的研讨会以传播关于保护臭氧层的信息。

行动计划

3. 在即将到来的巴西体制建设第五阶段里，巴西政府将继续通过其国家臭氧机构，促进臭氧层的保护，以期在 2007 年实现完全淘汰。目前，巴西正在努力制定加速淘汰时间表。就旨在对家用和商用制冷领域的制冷工人进行培训的项目而言，维修行业将是一个主要重点。第五阶段还会分配一些回收和再循环机器，并建立五个回收中心，以便为氟氯化碳消费量较高的地区的家用和商用制冷部门提供服务。同样，它还会重点关注汽车空调行业，在该行业里，他们鼓励在氟氯化碳再循环中心开展回收工作。在此期间，会就计量吸入器的用途进行详细的市场调研，以了解巴西计量吸入器生产过程中氟氯化碳的使用情况。

哥伦比亚：延长体制建设

项目摘要和国家概况	
执行机构：	开发计划署
以前核准的体制建设供资数额（美元）： 第一阶段：1994 年 3 月 第二阶段：1998 年 3 月 第三阶段：2000 年 3 月 第四阶段：2002 年 11 月 第五阶段：2005 年 4 月 共计	 317,790 212,000 212,000 275,600 275,600 1,292,990
延长所需数额（第六阶段）（美元）：	275,600
第六阶段建议核准数额（美元）：	275,600
机构支助费用（美元）：	20,670

多边基金体制建设第六阶段总成本（美元）：	296,270
由于体制建设第六阶段同等数量氟氯化碳淘汰成本为 12.1 美元/公斤（ODP 吨）：	暂缺
国家方案核准日期：	1994 年 3 月
国家方案报告的 ODS 消费量（1992 年）（ODP 吨）：	1,973.6
最近报告的 ODS 消费量（2005 年）（ODP 吨）：	709.3
受控物质基准消费量（ODP 吨）： (a) 附件 A 第一类物质（氟氯化碳）（1995-1997 年平均数） (b) 附件 A 第二类物质（哈龙）（1995-1997 年平均数） (c) 附件 B 第二类物质（四氯化碳）（1998-2000 年平均数） (d) 附件 B 第三类物质（三氯乙酸）（1998-2000 年平均数） (e) 附件 E（甲基溴）（1995-1998 年平均数）	 2,208.2 187.7 6.1 0.6 110.1
受控物质的最近消费量（2005 年）（ODP 吨）： (a) 附件 A 第一类物质（氟氯化碳） (b) 附件 A 第二类物质（哈龙） (c) 附件 B 第二类物质（四氯化碳） (d) 附件 B 第三类物质（三氯乙酸） (e) 附件 E（甲基溴） (f) 附件 C 第一类物质（氟氯烃）	 556.9 0.0 0.3 0.0 0.0 152.1
核准的项目供资数额（美元）：	21,009,985
支付的数额（截至 2007 年 3 月）（美元）：	14,830,664
将淘汰的 ODS（ODP 吨）：	1,861.3
已淘汰的 ODS（截至 2007 年 3 月）（ODP 吨）：	1,042.0

4. 活动摘要及执行委员会核准的供资数额：

活动摘要		核准的供资数额（美元）
(a)	投资项目：	18,646,360
(b)	体制建设：	1,445,921
(c)	项目编制、技术援助、培训和其他非投资项目：	917,704
	共计：	21,009,985

进度报告

5. 哥伦比亚体制建设项目第五阶段期间，国家臭氧机构继续积极工作，以遵守《蒙特利尔议定书》淘汰时间表。结果，哥伦比亚履行了在 2005 年削减 50%的氟氯化碳和四氯化碳的措施，并已开始实施一项综合性计划，以遵守随后的 2007 年削减量。在该阶段里，哥伦比亚政府继续改善法律框架以支持淘汰消耗臭氧层物质的工作，并继续成功地协调个别和总体性的投资项目。泡沫塑料行业的最终总体项目和最后一个商业制冷项目都已完工，其中，后者是国家淘汰计划的一部分。开始实施国家淘汰计划时，成立了多个区域中心，它们负责帮助：查明需要培训的其他技师，更好地了解不同地区的维修行业，扩大活动的影响并更好地控制消耗臭氧层物质的消费量。正如在前几个阶段里一贯表现的那样，国家臭氧机构通过电视台/电台、报纸、公开演讲和纪念国际臭氧日，积极地实施了各种公众意识活动。

行动计划

6. 由于哥伦比亚将于 2009 年年底之前完全淘汰氟氯化碳，该国体制建设的第六阶段将具有特别重要的意义。在该阶段里，哥伦比亚政府将通过其国家臭氧机构，致力于加强和确保作为国家淘汰计划一部分在维修行业实施的各种活动的可持续性，加强支持这些活动的法律框架，开始在最终用户部门开展活动，并增强消耗臭氧层物质的贸易和进口。国家淘汰计划的各项活动将继续通过各区域协调中心实施，以确保在各区域的影响。在第六阶段，哥伦比亚还将合并各种战略，以便在消费量较低（如四氯化碳）、且开发计划署将实施投资项目的行业淘汰消耗臭氧层物质。

附件二

执行委员会对提交给第五十二次会议的延长体制建设项目的看法

巴西

1. 执行委员会审查了巴西请求延长体制建设项目的最终报告，并赞赏地注意到巴西的国家臭氧机构在执行第四阶段期间取得了显著成果。特别是，执行委员会注意到了巴西所取得的进展，即把其 CFC-12 的消费量从 1999 年的 8,052 ODP 吨减少到了 2006 年的 477.8 ODP 吨，这一消费水平低于削减 50%以后的消费量。此外，执行委员会还注意到了重要消耗臭氧层物质消费行业的淘汰项目的执行进度，包括完成了泡沫塑料行业的各项活动，以及继续根据国家氟氯化碳淘汰计划在维修行业开展活动。执行委员会称赞了巴西政府在当前阶段取得的成就，并表示期望巴西在今后两年里继续实施其方案活动并取得显著进展，同时维持并突破其当前的氟氯化碳削减水平。

哥伦比亚

2. 执行委员会审查了哥伦比亚请求延长体制建设项目的最终报告，并赞赏地注意到哥伦比亚的国家臭氧机构在执行第五阶段期间取得了显著成果。特别是，执行委员会注意到了哥伦比亚为努力在 2005 年削减 50%的氟氯化碳消费量和 85%的四氯化碳消费量并在 2006 年继续遵守所有受控物质领域已确立的时间表而取得的进展。此外，执行委员会还注意到了重要消耗臭氧层物质消费行业的淘汰项目的执行进度，包括完成了泡沫塑料行业的最终总体项目，以及继续通过已建立的区域中心根据国家氟氯化碳淘汰计划开展活动。执行委员会称赞了哥伦比亚政府在当前阶段取得的成就，并表示期望哥伦比亚在今后两年里继续实施其方案活动并取得显著进展，同时维持并突破其当前的氟氯化碳削减水平。

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EXECUTIVE COMMITTEE OF THE MULTILATERAL FUND FOR THE IMPLEMENTATION OF THE MONTREAL PROTOCOL
(52nd Meeting, 23 – 27 July 2007, Montreal)

2007 WORK PROGRAMME AMMENDMENT

OF THE

UNITED NATIONS DEVELOPMENT PROGRAMME

Request for Project Preparation and Non-Investment Projects at the 52nd Executive Committee Meeting

Submitted 28 May 2007
Revised 21 June 2007

2007 UNDP WORK PROGRAMME AMMENDMENT

52nd Executive Committee Meeting (23 – 27 July 2007, Montreal)

This Work Programme document contains all non-investment and project preparation programmes that are being requested at the 52nd Meeting of the Executive Committee. These requests amount to US$ 756,600 plus US$ 56,745 of support cost, as elaborated upon below.

1) Institutional Strengthening Renewal Requests.

The following Institutional Strengthening Renewal Requests are being submitted at the 52nd meeting of the Executive Committee:

Nr	COUNTRY	TITLE	ODP	BUDGET	SUPPORT COST	TOTAL
1	Brazil	Institutional Strengthening Phase V		351,000	26,325	377,325
2	Colombia	Institutional Strengthening: Phase VI		275,600	20,670	296,270
Sub Total Institutional Strengthening Projects				**626,600**	**46,995**	**673,595**

Documents for the IS Renewal Requests have been submitted separately by UNDP.

2) Requests for Technical Assistance Projects.

There will be no submission of Technical Assistance Projects to the 52nd Executive Committee Meeting.

3) Requests for Project Preparation in the Refrigeration Servicing Sector.

There will be no submission of Project Preparation Funds for the Refrigeration Servicing Sector to the 52nd Executive Committee Meeting.

4) Requests for Activities in the MDI Sector.

Nr	COUNTRY	TITLE	BUDGET	SUPPORT COST	TOTAL	REMARKS
1	Colombia	PRP for MDI Investment Project	30,000	2,250	32,250	Details in Annex 1
2	India	PRP for MDI Investment Project	100,000	7,500	107,500	Details in Annex 2
Subtotal PRP-Proposals (Other Sectors)			**130,000**	**9,750**	**139,750**	

Project preparation requests listed above are related to the development of investment projects

for Metered Doses Inhalers (MDIs). Funds would be used for international consultants, national consultants, stakeholders workshops and sundries. Based on precedent experience the level of funds requested for PRP activities for MDI is higher than the level of funds requested for PRP activities in other sectors due to the level of fees for international experts on this field, which is higher than in other fields due to its very specialized nature. In the case of India there will be seven companies involved in different cities, for this reason the level of funds requested is higher than in the other two countries.

Detailed information required to submit these preparation activities as per Decision 51/34 of the Executive Committee is available in Annex 1 (Colombia) and Annex 2 (India).

ANNEX 1

COLOMBIA MDI

Justifications for the need to receive assistance by India for phasing out of CFC in MDI sector as required under decision 51/34 Para (c).

Colombia became aware of the CFC consumption in the MDI sector after the approval of the National Phase Out Plan in 2003. During the collection of data undertaken for the preparation of the NPP, the company Chalver consuming CFC in the manufacturing of MDI was not identified as it had recently started production and it was not very well known as a MDI producer yet. By the time the company started to establish its production line of MDI (2001 – 2002), HFA technologies were not available in developing countries, only few companies in Article 5 countries had developed this technology. Since the confirmation of the CFC consumption in the MDI sector in Colombia by Chalver, this consumption has been yearly reported to the Multilateral Fund Secretariat as part of the Country Programme Implementation Report.

Chalver is the only local company manufacturing CFC MDI in the country.

The adaptation of HFA-based MDI propellant technology in developing countries is a recent phenomenon and has not yet been fully deployed. It would take about 2-3 years to fully convert from CFC-based MDI to HFC-based MDI technology (including the time taken to register and launch the final approved and reformulated product in the market). The industries are not fully equipped to transit cost-effectively from CFC-based MDIs within the timeframe available, especially against the background of rapidly growing demand.

In view of above, the Executive Committee may be requested to consider Colombia's proposal for project preparation funding in light of the paragraph 1 and 2 of Decision XVIII/16 of the 18th Meeting of the Parties (MOP) and Decision 51/34 of the Executive Committee.

Information as required by the Executive Committee (ExCom) under its Decision 51/34 (Para C)

I. Name of nationally owned CFC-MDI manufacturing facilities, the date when the CFC production lines were established and the production capacity of each production line

BASIC INFORMATION	
Name	**LABORATORIOS CHALVER DE COLOMBIA S.A**
I.D.	**890.203.194-1**
Address	**Av. 68 No. 37B –31 Sur**
Date of establishment of the production line	**There is one production line established in the year 2002**
Production Capacity for each line	**The operational capacity of the production line is between 2000 and 3000 units/hour.**

II. Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/year)

Pharmaceutical Form	**Active Ingredients**	**Propellant used**	**Annual Production 2006 (units/year)**
Aerosol Nabumex	Beclomethasone Dipropionate	Diclorodifluoromethane Triclorofluoromethane	9,000
Aerosol Aspromio	Ipratropium Bromide	Diclorodifluoromethane Triclorofluoromethane	12,000
Aerosol Airmax	Salbutamol	Diclorodifluoromethane Triclorofluoromethane	72,000
Aerosol Oxitone	Salbutamol+ Beclomethasone	Diclorodifluoromethane Triclorofluoromethane	15,000
Aerosol Salpromio	Salbutamol+ Ipratropioum Bromide	Diclorodifluoromethane Triclorofluoromethane	5,000
Aerosol Inflabon	Budesonide	Diclorodifluoromethane Triclorofluoromethane	0
Aerosol Frudexan	Fluticasone	Diclorodifluoromethane Triclorofluoromethane	0
Aerosol (Undetermined)	Formoterol Fumarate + Budesonide	Diclorodifluoromethane Triclorofluoromethane	0
TOTAL			113,000

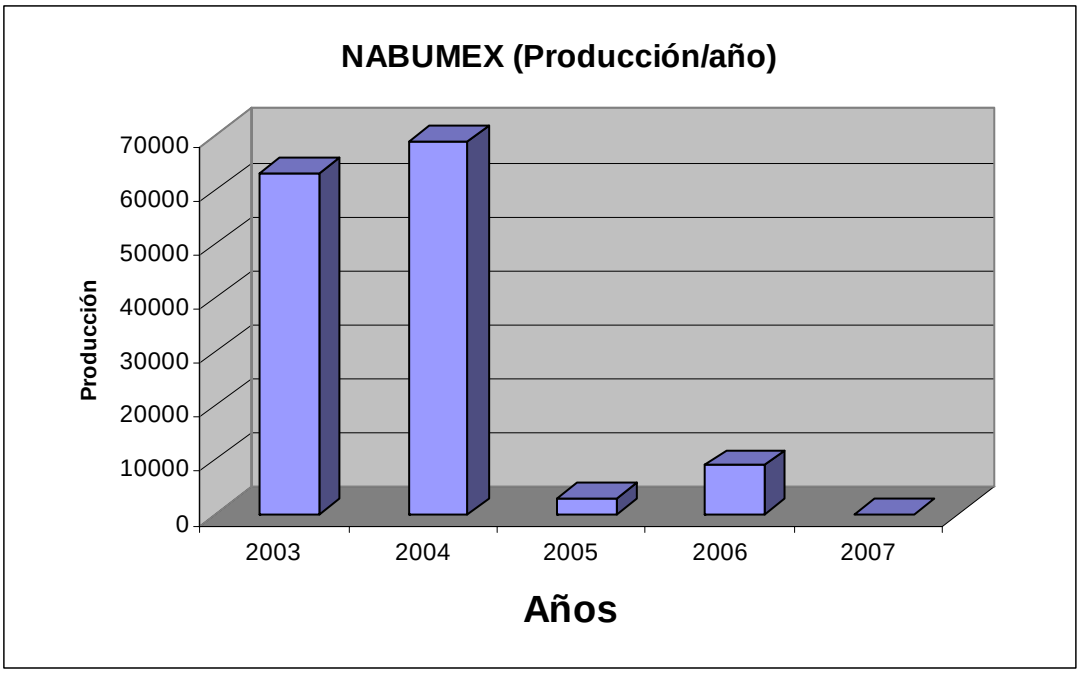
III. Growth patterns of CFC- MDI production over the past three years

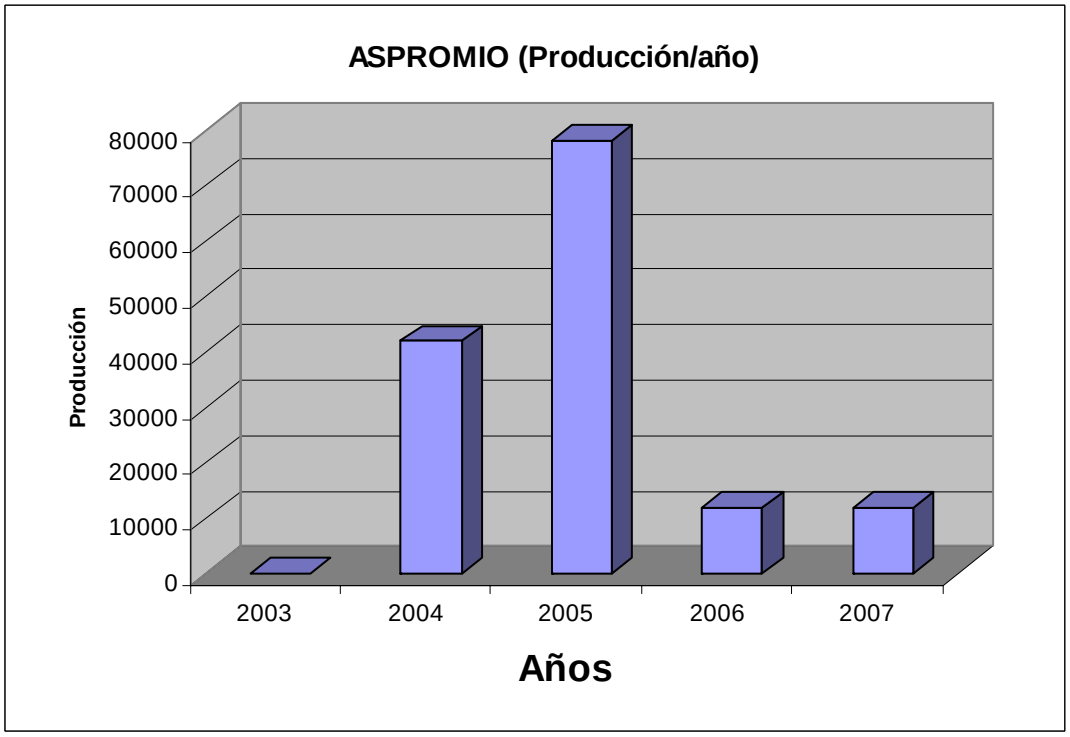
Pharmaceutical Form	Annual Production (units / year)				
	2003	2004	2005	2006	2007 (*)
Aerosol Nabumex	63,000	69,000	3,000	9,000	-
Aerosol Aspromio	-	42,000	78,000	12,000	12,000
Aerosol Airmax	144,000	300,000	-	72,000	40,000
Aerosol Oxitone	6,000	3,000	36,000	15,000	6,000
Aerosol Salpromio	-	-	10,000	5,000	3,000
Aerosol Inflabon	-	-	-	-	-
Aerosol Frudexan	-	-	-	-	-
Aerosol (Undetermined)	-	-	-	-	-
TOTAL	213,000	414,000	127,000	113,000	61,000

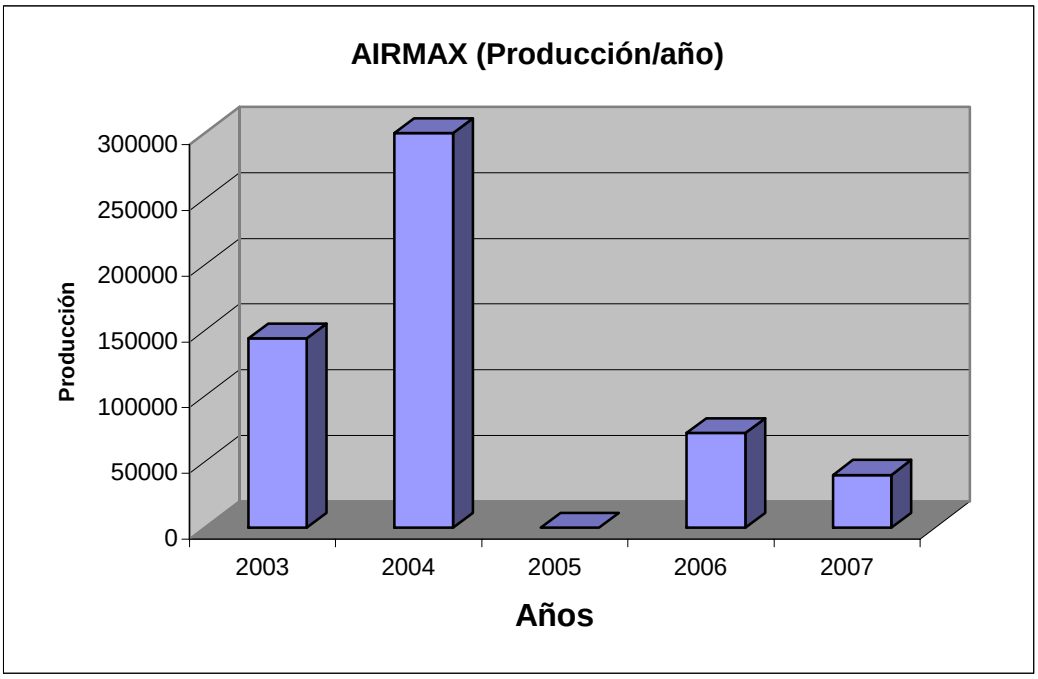
Production levels have decreased due to import of CFC MDI from India at very low cost levels. Laboratorios Chalver is the only national producer of MDIs.

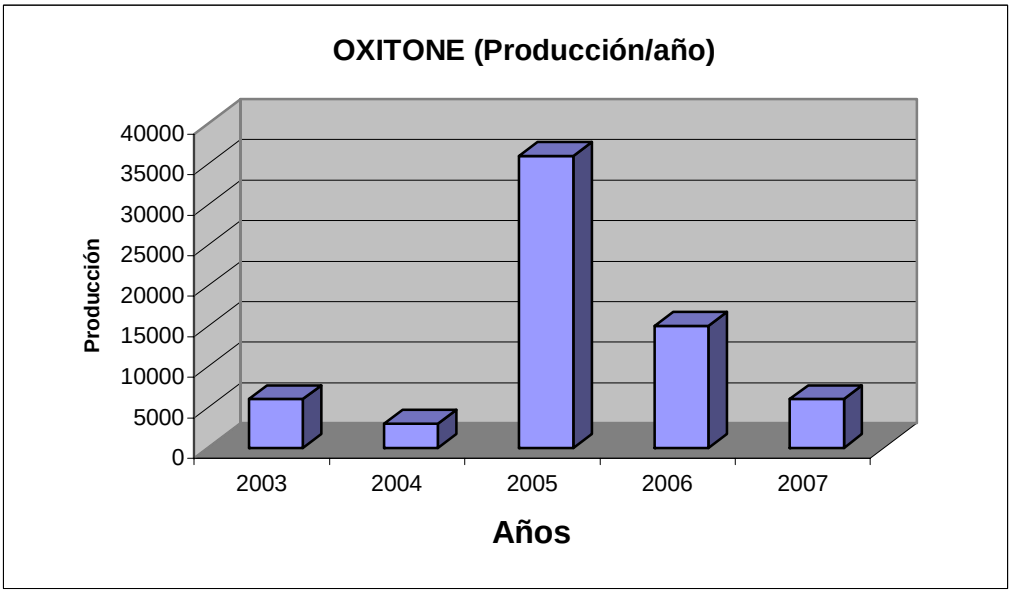
The MDI produced in 2004 has the following distribution:

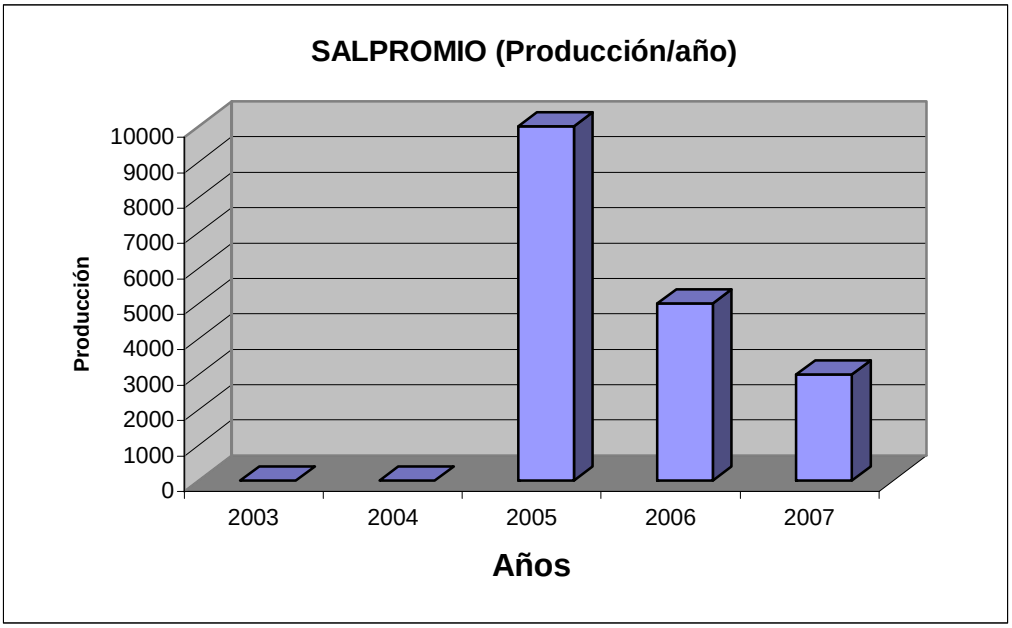
Amounts	Percentage	Market
265.000 Units	59.15 %	Nacional Market
183.000 Units	40,85%	Export to other Article 5 Parties.


NABUMEX (Producción/año)
Producción
70000
60000
50000
40000
30000
20000
10000
0
2003
2004
2005
2006
2007
Años


ASPROMIO (Producción/año)
Producción
80000
70000
60000
50000
40000
30000
20000
10000
0
2003
2004
2005
2006
2007
Años


AIRMAX (Producción/año)
Producción
300000
250000
200000
150000
100000
50000
0
2003
2004
2005
2006
2007
Años


OXITONE (Producción/año)
Producción
40000
35000
30000
25000
20000
15000
10000
5000
0
2003
2004
2005
2006
2007
Años



Consumption in the sector has accordingly been reported as part of the CP implementation Report submitted to the Multilateral Fund Secretariat as follows:

Substance	2003	2004	2005	2006
CFC 11	**2.52**	**2.80**	**0.80**	**0.56**
CFC 12	**3.56**	**5.28**	**1.00**	**1.65**
Total	6.08	8.08	1.80	2.21

IV. Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC MDIs and what those alternatives were

Laboratorios CHALVER is considering undertaking the retrofit of the production line in order to be able to produce HFA MDI. As part of this process the company has expressed particular concern on the development of the HFA formulations. The company has not been able to undertake the conversion to HFA MDI for several reasons, the first one that it does not have the corresponding formulations, the second that the new product would have still a higher price in the market and the company has already reduced its production due to competition with CFC MDI product imported a very low price.

V. Each production facility plans for phasing out CFC consumption

Production Line	Plan to eliminate consumption of CFC	Time	Cost
Línea 1 Pamasol mixing vessel filler, crimper.	Retrofitting of certain line components in order to be able to produce alternative HFA MDI drugs equivalent to the CFC MDI drugs currently produced.	2-3 years	To be determined depending on alternative formulations

The necessary changes for the conversion to HFA will consist mostly on modifications to the production line, mainly the change in the dose pumps and the filling head.. It has not been determined if a new vessel is required, and this will depend on the formulation selected during the preparation of the project. In addition to the incremental capital costs mentioned the company will incur in costs for the development of the new formulations and developing of the HFA products based on the formulations. The company will require assistance from a technology provider to develop the new products, but will not have to outsource the whole process as it has adequate laboratories to undertake part of the development activities, reducing costs.

VI. The number of non-CFC MDIs and dry-powder inhalers sold or distributed within the Party, by active ingredient, brand/manufacturer, and source

The company is not producing HFA MDI medication and has not reported any production of Dry Powder Inhalers. Multinational companies affiliated to IPAC have reported imports of the alternatives below, however the volume of imports is not known yet:

HFA MDI Beclomethasone DP.
DPI Budesonide
DPI Budesonide & Formoterol
DPI Fluticasone P.
HFA MDI Fluticasone P.
HFA MDI Fluticasone/Salmeterol
DPI Fluticasone/Salmeterol
DPI Formoterol
DPI Salbutamol
HFA Salbutamol
DPI Salmeterol
DPI Terbutaline

The information available on imports is presented inthtable below:

Ingrediente activo	Fabricante	Propulsor	Inhaladores de dosis medida importados/año		
			2003	2004	2005
Salbutamol Micronizado	Glaxo Wellcome Mexico S.A. De C.V.	Triclorofluorometano, Diclorofluorometano			173,799
Salbutamol	Cipla Limited	Monofluorotriclorometano, Diflurodiclorometano			204,430
Salbutamol	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			288,646
Salbutamol	Merck	Difluorodiclorometano, Monofluorotriclorometano			300,497
Salbutamol	Medyspray Laboratories Private Limited	Difluorodiclorometano, Monofluorotriclorometano			90,953
Salmeterol	Glaxosmithklaine	Difluorodiclorometano, Monofluorotriclorometano			40,077
Bromuro De Ipratropio	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			92,171
Budesonida	Laboratorios Biogen De Colombia S.A. (Importador)	Difluorodiclorometano, Monofluorotriclorometano			44,166
Budesonida Micronizada	Boehringer Ingelheim International	Difluorodiclorometano, Monofluorotriclorometano			148,787
Propionato De Fluticasona (Micronizado)	Glaxosmithklaine	Difluorodiclorometano, Monofluorotriclorometano			60,423
Bromuro De Ipratropio	Mckesson	Difluorodiclorometano, Monofluorotriclorometano			56,841
Bromuro De Ipratropio	Cipla Limited	Difluorodiclorometano, Monofluorotriclorometano			41,336
Beclometasona Dipropionato	Laboratorios Aldo Union S.A.	Difluorodiclorometano, Monofluorotriclorometano			12,634
Beclometasona Dipropionato	Cipla Limited	Monoflurotricloro Metano, Diflurodicloro Metano			40,510
Bromuro De Ipratropio	Boehringer Ingelheim Do Brasil Quimica E Farmaceutica Ltda	Tricloromonofluorometano, Tricloromonofluorometano/Diclorodifluorometano/1, 2-Diclorotetrafluoroetano			317,655

ANNEX 2
INDIA MDI

Justifications for the need to receive assistance by India for phasing out of CFC in MDI sector as required under decision 51/34 Para (c).

India became aware of high CFC consumption in its pharmaceutical MDI sector in 2006 while collecting information for preparation of the country program progress report for 2005. The CFC consumption in 2005 was reported to the Fund Secretariat. Further, in response to the Secretariat's questionnaire circulated during the network meeting held in Colombo during 4-8 December, 2007, the detailed information was sent to the Secretariat. Based on the information, the MLF Secretariat had prepared the document no. 51/39 for the consideration of the 51st Executive Committee meeting.

Constraints on accurately establishing consumption

Due to the rapidly rising demand for MDI products due to the growing incidence of asthma and related diseases with significant public health and social implications, the consumption of CFC-based MDIs has grown quite significantly. At the time of approval of India's NCCOPP, the estimated consumption was not significant and therefore it was considered by the Government not to seek additional funding. However, presently, with more accurate estimates of consumption, which is significantly high (over 700 tonnes annually) and consequent implications/challenges for the health services in the country, and due to the technological and financial constraints for cost-effective conversion to HFC-based MDI technology, the Government now seeks the assistance of MLF in addressing this consumption.

Technology constraints

The first HFC-based propellants for MDIs were developed only in 1995 and the technology was established and made commercially viable by 2000. The adaptation of HFC-based MDI propellant technology in developing countries is a recent phenomenon and has not yet been fully deployed. It would take about 2-3 years to fully convert from CFC-based MDI to HFC-based MDI technology (including the time taken to launch the final approved and reformulated product in the market). The industries are not fully equipped to transit cost-effectively from CFC-based MDIs within the timeframe available, especially against the background of rapidly growing demand.

The high consumption of CFC in MDI sector and looking at possibilities of its increase in future years would result in potential non-compliance for India in 2007 and future years.

In view of above, the Executive Committee may be requested to consider India's proposal for project preparation funding in light of the paragraph 1 and 2 of Decision XVIII/16 of the 18th Meeting of the Parties (MOP) and Decision 51/34 of the Executive Committee.

Information as required by the Executive Committee (ExCom) under its Decision 51/34 (Para C)

I. Name of nationally owned CFC-MDI manufacturing facilities, the date when the CFC production lines were established and the production capacity of each production line

S. No.	Name of the MDI Manufacturers	Percentage of National Ownership	Date of Establishment	Production capacity
1	AstraZeneca Pharma India Ltd.	10%	Nov-81	Production at own location until 2005. Since 2006 products made on loan basis at Midas Care
2	Cadila Health Care Ltd.	100%	15-May-95	1 production line with 8 million units/year
3	Cipla Ltd., Kurmumbh, Mh	100%	Nov-93	3 production lines each with 20 million units/year; 1 production line with 10 million units/year Total: 70 million units/year
	Cipla Ltd., Kundaim, Goa	100%	17-Oct-97	
	Cipla Ltd., Verna, Goa	100%	11-Jan-00	
4	GlaxoSmithkline Pharmaceuticals Ltd.	49.3%	1990	1 production line with 3 million units/year
5	Midas Care Pharmaceuticals Pvt. Ltd.	100%	1993-94	2 production lines each with 7.5 million units/year Total 15 million units/year
6	Natco Pharma Ltd.	70%	1981	1 production line with 3 million units/year
7	Sun Pharmaceutical Industries Ltd.	100%	2001-2005	1 production line with 2 million units/year

II. Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/year)

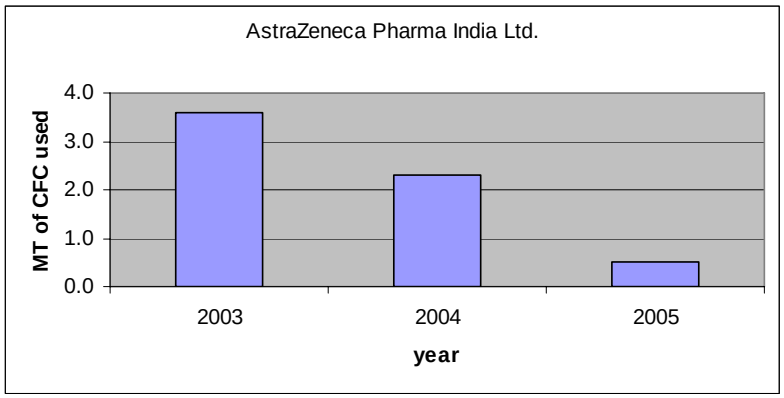
S.No.	Name of the MDI Manufacturers	By Active Ingredients	Annual Production output (unit/year)
1	AstraZeneca Pharma India Ltd.	1.Budesonide 2.Terbutaline Sulphate	Products manufactured on loan basis CFC Consumption: 2003: 3.4 MT 2004: 2.3 MT 2005: 0.5 MT
2	Cadila Health Care Ltd.	1.Budesonide BP 2.Budesonide BP + Formoterol Fumarate 3.Formoterol Fumarate 4.Ipratropium Bromide BP 5.Salbutamol Sulphate IP + Ipratropium Bromide 6.Salmeterol Xinafoate + Fluticasone Propionate	1.2 million units/year CFC Consumption: 2003: 3.2 MT 2004: 4.9 MT 2005: 8.1 MT
3	Cipla Ltd., Kurmumbh, Mh	1.Beclomethasone Dipropionate 2.Beclomethasone Dipropionate + Salbutamol 3.Budesonide 4.Fluticasone Propionate 5.Ipratropium Bromide 6.Salbutamol 7.Salmeterol Xinafoate	42 million units/year CFC Consumption: 2003: 573 MT 2004: 688 MT 2005: 674 MT
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Beclomethasone + Salbutamol 3.Budesonide 4.Budesonide + Formoterol 5.Fluticasone + Salmetrol 6.Formoterol 7.Ipratropium Bromide 8.Salbutamol 9.Salmeterol	
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Beclomethasone Dipropionate + Salbutamol 3.Budesonide 4.Fluticasone Propionate 5.Formoterol Fumarate 6.Ipratropium Bromide 7.Levosalbutamol 8.Salbutamol 9.Salbutamol + Ipratropium Bromide 10. Salmeterol Xinafoate 11. Salmeterol + Fluticasone Propionate 12. Sodium Cromoglicate 13. Tiotropium Bromide 14. Tiotropium Bromide + Formoterol Fumarate	
4	GlaxoSmithkline Pharmaceuticals Ltd.	1.Beclomethasone 2.Salbutamol	0.8 million units/year CFC Consumption: 2003: 29 MT 2004: 25 MT 2005: 28 MT
5	Midas Care Pharmaceuticals Pvt. Ltd.	1.Beclomethasone 2.Budesonide 3.Cicllesonide 4.Fluticasone 5.Formoterol 6.Formoterol + Budesonide 7.Ipratropium Bromide	2 million units/year CFC Consumption: 2003: 18.8 MT 2004: 21.3 MT 2005: 29.8 MT

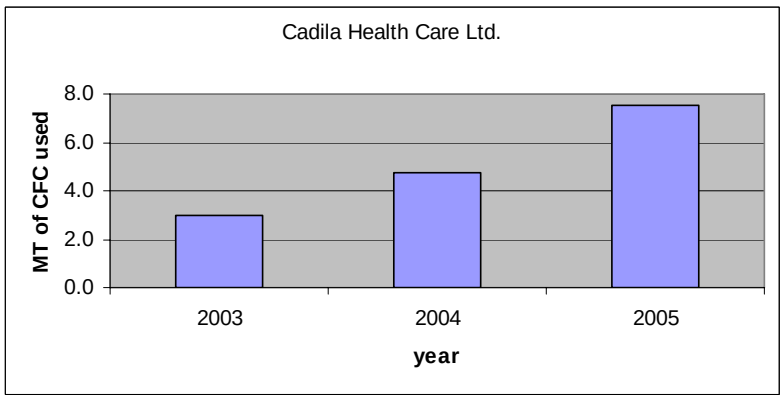
		8.Ipratropium + Salbutamol 9.Salbutamol 10.Salbutamol + Beclomethasone 11.Salmeterol + Fluticasone 12.Sodium Cromoglicate 13.Terbutaline 14.Tiotropium Bromide 15.Tiotropium Bromide + Formoterol	
6	Natco Pharma Ltd.	1.Beclomethasone 2.Salbutamol	10,000 units/year CFC Consumption: 2003: 3.32 MT 2004: 1.08 MT 2005: 0.98 MT
7	Sun Pharmaceutical Industries Ltd.	1.Budesonide 2.Budesonide + Formoterol Fumarate 3.Fluticasone Propionate 4.Fluticasone Propionate + Salmeterol Hydroxy Napthoate 5.Salbutamol 6.Salmeterol Hydroxy Napthoate 7.Tiotropium Bromide Monohydrate 8.Tiotropium Bromide Monohydrate + Formoterol Fumarate	0.4 million units/year CFC Consumption: 2003-2004: 8.3 MT 2004-2005: 7.2 MT 2005-2006: 6.9 MT

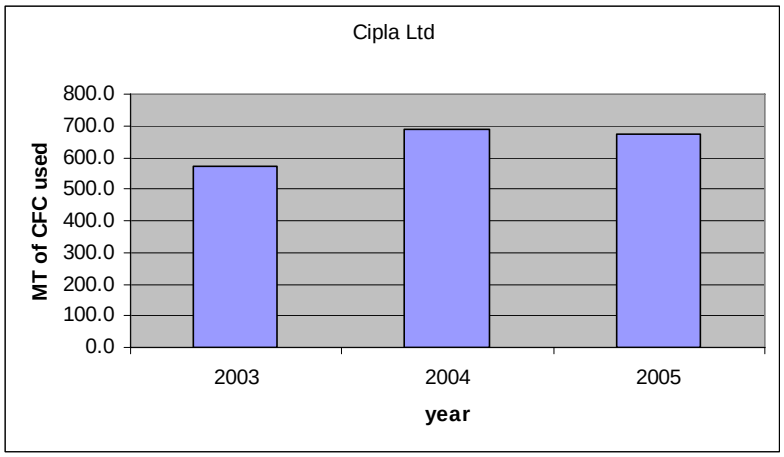
III. Growth patterns of CFC-MDI production over the past three years (2003-2005), based on consumption of CFC in MDI manufacturing, are indicated in the table below. It is noted that as CFC consumption differs in different formulations and among different industries, the "units of CFC-MDI produced" without being properly verified by the Ozone Cell, do not truly reflect the demand on CFC and thus the CFC phase-out efforts required.

Name of Companies	Quantity of CFCs (MT) used for MDI Production		
	2003	**2004**	**2005**
AstraZeneca Pharma India Ltd.	3.6	2.3	0.5
Cadila Health Care Ltd.	3.0	4.8	7.5
Cipla Ltd	573.0	688.0	674.0
GlaxoSmithkline Pharmaceuticals Ltd.	29.2	24.6	27.6
Midas Care Pharmaceuticals Pvt. Ltd.	18.8	21.3	29.8
Natco Pharma Ltd.	3.3	1.1	1.0
Sun Pharmaceutical Industries Ltd.	8.3	7.2	6.9

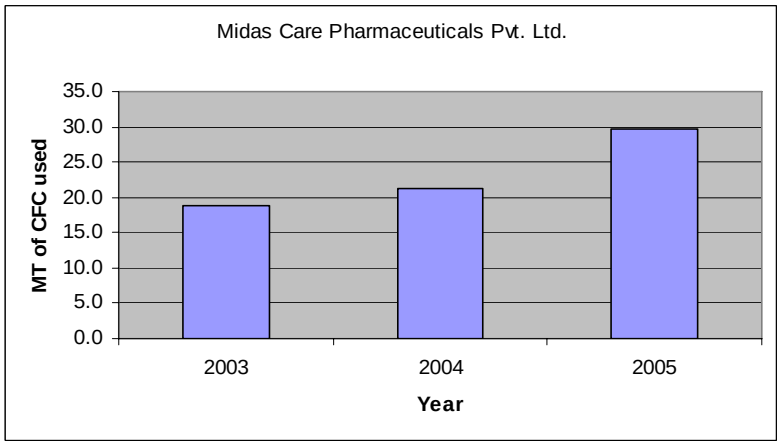
Growth patterns in graphical representation for each plant.

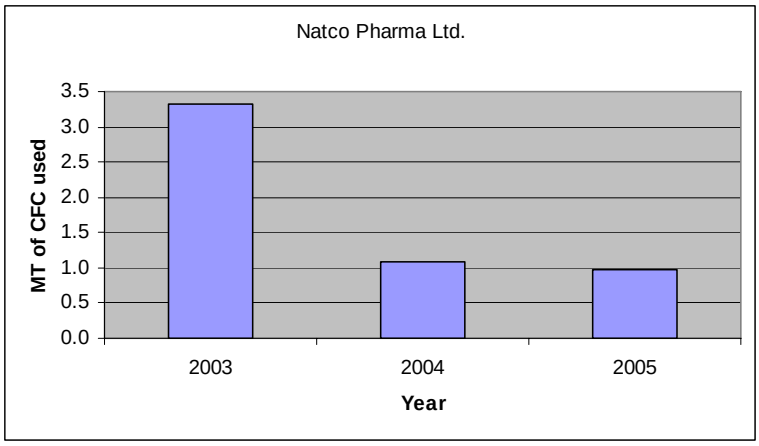


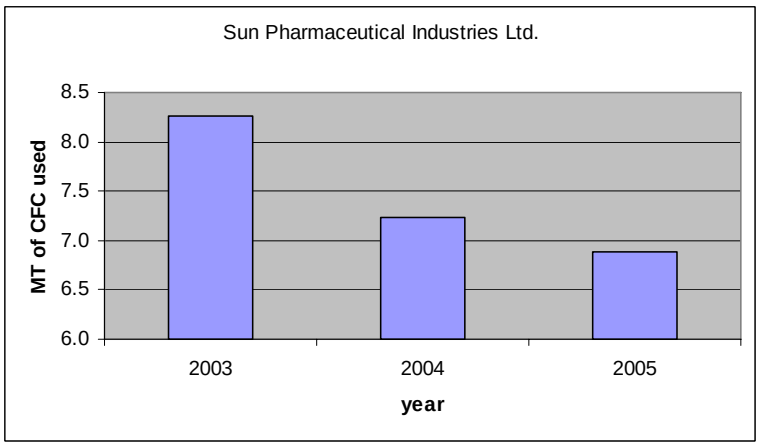



Cipla Ltd
800.0
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
MT of CFC used
2003
2004
2005
year


GlaxoSmithkline Pharmaceuticals Ltd.
30.0
29.0
28.0
27.0
26.0
25.0
24.0
23.0
22.0
MT of CFC used
2003
2004
2005
Year


Midas Care Pharmaceuticals Pvt. Ltd.
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
MT of CFC used
2003
2004
2005
Year


Natco Pharma Ltd.
MT of CFC used
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
2003
2004
2005
Year


Sun Pharmaceutical Industries Ltd.
MT of CFC used
8.5
8.0
7.5
7.0
6.5
6.0
2003
2004
2005
year

IV. Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC MDIs and what those alternatives were

S.No.	Name of the MDI Manufacturers	Alternatives to CFC MDIs by active ingredient using HFA
1	AstraZeneca Pharma India Ltd.	NIL
2	Cadila Health Care Ltd.	NIL
3	Cipla Ltd., Kurmumbh, Mh	NIL
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Budesonide 3.Budesonide + Formoterol 4.Fluticasone 5.Salbutamol
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Ipratropium Bromide 3.Salbutamol 4.Salbutamol + Ipratropium Bromide 5.Salmeterol Xinafoate 6.Salmeterol + Fluticasone Propionate
4	GlaxoSmithkline Pharmaceuticals Ltd.	NIL
5	Midas Care Pharmaceuticals Pvt. Ltd.	1. Formoterol + Budesonide 2. Fluticasone 3.Cicllesonide 4.Salbutamol 5.Salmeterol + Fluticasone
6	Natco Pharma Ltd.	1.Beclomethasone 2.Salbutamol Sulphate
7	Sun Pharmaceutical Industries Ltd.	1.Cicllesonide

V. Each production facility plans for phasing out CFC consumption

S.No.	Name of the MDI Manufacturers	Plan for phasing out CFC consumption	Time	Cost
1	AstraZeneca Pharma India Ltd.	No	-	-
2	Cadila Health Care Ltd.	Yes*	2-3 yrs	Rs. 30 crores
3	Cipla Ltd., Kurmumbh, Mh	Yes*	10 yrs	Rs. 90 crores
	Cipla Ltd., Kundaim, Goa	Yes*		
	Cipla Ltd., Verna, Goa	Yes*		
4	GlaxoSmithkline Pharmaceuticals Ltd.	No	-	-
5	Midas Care Pharmaceuticals Pvt. Ltd.	Yes*	3 yrs	Rs. 5 cr (capital expenditure)
6	Natco Pharma Ltd.	Yes*	3 yrs	USD 3.37 million for equipment
7	Sun Pharmaceutical Industries Ltd.	Yes*	1½ yrs	Rs. 250 lacs capital cost

** All plans are attached in Appendix-1.*

VI. The number of non-CFC MDIs and dry-powder inhalers sold or distributed within the Party, by active ingredient, brand/manufacturer, and source

S.No.	Name of the MDI Manufacturers	No. of non-CFC MDIs sold in India (By active ingredient) (Year 2006)	Dry-powder inhalers sold (Year 2006)
1	AstraZeneca Pharma India Ltd.	NA	NA
2	Cadila Health Care Ltd.	NA	Yes
3	Cipla Ltd., Kurmumbh, Mh	NA	1.Beclomethasone 2.Budesonide 3.Cicllesonide 4.Cicllesonide + Formoterol 5.Fluticasone Propionate 6.Formoterol Fumarate + Budesonide 7.Ipratropium Bromide 8.Levosalbutamol 9.Levosalbutamol + Ipratropium Bromide 10.Salbutamol 11.Salbutamol + Beclomethasone 12.Salmeterol Xinafoate 13. Salmeterol + Fluticasone 14. Tiotropium Bromide 15. Tiotropium + Formoterol Fumarate
	Cipla Ltd., Kundaim, Goa	1.Beclomethasone 2.Budesonide 3.Budesonide + Formoterol 5.Fluticasone 6.Salbutamol	
	Cipla Ltd., Verna, Goa	1.Beclomethasone Dipropionate 2.Ipratropium Bromide 3.Salbutamol 4.Salbutamol + Ipratropium Bromide 5.Salmeterol Xinafoate 6. Salmeterol + Fluticasone Propionate	
4	GlaxoSmithkline Pharmaceuticals Ltd.	NIL	NA
5	Midas Care Pharmaceuticals Pvt. Ltd.	163494 units/year 1.Cicllesonide 2.Fluticasone 3.Formoterol + Budesonide 4.Salbutamol 5. Salmeterol + Fluticasone	NA
6	Natco Pharma Ltd.	NIL	NA
7	Sun Pharmaceutical Industries Ltd.	NIL	NA

Non-CFC MDIs are produced by 2 companies: Cipla and Midas Care. There is no Non-CFC MDI import into India.

Cipla produces “Beclomethasone, Budesonide, Budesonide + Formoterol, Fluticasone, Salbutamol, Ipratropium Bromide, Salmeterol Xinafoate” formulations and a total of 36,000 units/year.

Active ingredient wise numbers are presented in the table below

Cipla - Kundaim, Goa	
Active Ingredient (Manufactured)	**Units (2005)**
Salbutamol	2270000
Budesonide	8695000
Beclomethasone	40000
Budesonide + Formoterol	34000
Fluticasone	18000
Cipla - Verna, Goa	
Active Ingredient (Manufactured)	**Units (2005)**
Beclomethasone Dipropionate	615632
Ipratropium Bromide	4600
Salbutamol	1226726
Salmetrerol Xinafote	1921
Salbutamol & Ipratropium Bromide	7480
Salmeterol & Fluticasone Propionate	8137
TOTAL	**~ 13 million units**

Midas Care produces “Cicllesonide, Fluticasone, Formoterol + Budesonide, Salbutamol, Salmeterol + Fluticasone formulations and a total of 1,63,494 units/year.

Active ingredient wise numbers are presented in the table below

Active Ingredient (Manufactured)	**Units (2005)**
Salbutamol	5000
Formoterol + Budesonide	20000
Salmetrerol + Fluticasone	10000
Fluticasone	
Cicllesonide	
TOTAL	**~ 35000**

Starting 2005, part of its production at Astra Zeneca is produced on loan basis at Midas Care. From last year i.e. 2006, Astra Zeneca switched its entire production on loan basis at Midas Care.

Appendix-1

Plan for phasing out CFC consumption

1. AstraZeneca Pharma India Ltd.

- No

2. Cadila Health Care Ltd.

- Estimated time required for implementing transition projects: Two to three years.
- Estimated cost of implementing transition projects: 30 crores (This includes all costs like Formulation Development/Analytical Development / Stability and equipment's).
- Projected activities required for smooth transition in India: Technology souring / Patent search / suitable equipment's / source of materials / Development studies / pilot scale studies / commercial production.

3. Cipla Ltd., Kurmumbh, Mh / Cipla Ltd., Kundaim, Goa / Cipla Ltd., Verna, Goa

- Estimated time required for implementing transition projects: 10 years.
- Estimated cost of implementing transition projects: In order to change over from CFC to HFA, we require the following funds.

Funds Requirement for the Transition to HFA		
	Item	**Funds Requirement (Rs. Crores)**
1.	HFA MDI filling machine and accessories - 3 Nos.	60
2.	High pressure manufacturing vessels - 6 Nos.	15
3.	Restructuring of manufacturing area*	10
4.	Patient & Doctors education#	5
	TOTAL COST (Rs. Crores)	**90**

* *Alcohol is used as co solvent, which require flame proof manufacturing area and also use of alcohol invites a higher excise duty whereby it will increase the cost of the product.*

\# *This includes cost to be incurred on account of promotional camps, literature printing & distribution, free supply of samples, traveling expenses etc.*

- Projected activities required for smooth transition in India: The following issues need to be resolved in order to ensure smooth transition.

  The development of CFC Free MDIs involves a lot of R & D development with all parts related to the metered dose inhaler.

  - **Development of New Formulations**

    The HFA gases have poor solubilities, hence formulator had to try new excipients such as alcohol, glycols etc. This took considerable time and effort as the stability of the formulation was carried out for almost 2 years per formulation. Moreover, the formulation needed to be efficacious and safe as the previous CFC formulations. The cost of HFA propellants is higher than the existing CFC propellants.

- **Development of Packaging Components (CAN, Valve and Actuator)**
  The use of new excipients, new propellants led to formulation issues to moisture ingress, stability, pressure, drug adhesion. This led to a whole new development of the metering valve, new elastomers, various special types of CANS (coated, anodized), changes in the design of the actuator. All of the components are imported which incur a high cost. As there are no Indian mfgrs. for the CAN and the Valve the MDI manufacturer will need subsidies from the Government of India on imported material required for CFC Free MDIs. At present the import duty is at 7.5%.

- **Development of Manufacturing Machinery (High pressure)**
  It involves the reorganizing of the manufacturing area, import of very expensive machinery, changes in the design of the machinery and the manufacturing vessels.

- **Development of New Filling Systems**
  Filling machinery and methods are required to be redesigned because of changes in pressure. The time frame for getting this new filling machinery is almost 2 years.

- **Development of New Testing Methods**
  New testing methods are needed to be developed and sensitive and highly sophisticated analytical instruments are required to be procured.

- **Clinical Trial Programmes**
  For the formulations developed Clinical Trial Programmes are required to determine the safety & efficacy of the HFA formulations.

- **Education programmes for Doctors & Patients**
  Resistance from medical fraternity for the change to HFA as CFC based MDIs are well established and time tested. Doctor needs to be educated on the new excipients used in HFA formulations. Resistance from patient can be anticipated as taste of the HFA formulation is different. Hence doctor and patient education will need to be done on a massive scale.

  HFA inhalers not economically viable (cost almost double that of CFC based inhalers).

  Thus an overall redevelopment programme needs to be put in place for transition to CFC Free MDIs. This is an ongoing process.

4. GlaxoSmithkline Pharmaceuticals Ltd

- No

5. Midas Care Pharmaceuticals Pvt. Ltd.

- Estimated time required for implementing transition projects: This may take around 3 years provided other supports are easily available.

- Estimated cost of implementing transition projects: This may be difficult, at this stage, for us to comment as many critical machineries and balancing equipments are not available locally and have to be imported. Still roughly the CAPEX cost of implementing transition project may be

around Rs. 5 cr and that this figure may change. Formulation development and other related costs will be extra depending on the molecules and formulations.

- Projected activities required for smooth transition in India: There are many activities required to achieve transition from CFC based MDIs to HFA based MDIs.

6. Natco Pharma Ltd.

- Estimated time required for implementing transition projects: 3 years.
- Estimated cost of implementation transition projects: USD 3.37 millions for equipment.
- Projected activities required for smooth transition in India: Facility Upgradation.

7. Sun Pharmaceutical Industries Ltd.

- Estimated time required for implementing transition projects: 18 months.
- Estimated cost of implementation transition projects
  - **Capital Cost**

    We have contacted the equipment manufacturers and taken some estimates of capital expenditure. The capital cost involved in switching from CFC to HFA will be approximate Rs. 250 lacs based on our current understanding. This may change in future, when we implement the project.

  - **Packaging material cost/Stability Studies/Analytical method development cost**

    For the above mentioned product, we have estimated that annual cost would be approximate Rs. 90 lacs. This again is approximate and may change in future, once the project is implemented.

- Projected activities required for smooth transition in India: Facility upgradation.
  - Evaluation of existing IPR
  - Primary packaging material selection (valve, can & actuators)
  - Analytical method development
  - Preformulation studies
  - Stability studies
  - Scale up
  - New equipments/Machineries for R&D and plant