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执行蒙特利尔议定书
多边基金执行委员会
第五十五次会议
2008 年 7 月 14 日至 18 日，曼谷

工发组织 2008 年工作方案修正案

基金秘书处的评论和建议

1. 工发组织请执行委员会核准其2008年工作方案修正案所需的12,495,760美元以及机构支助费用 938,682 美元。

2. 工发组织工作方案修正案拟议的活动如下文表 1 所示：

表 1：工发组织的工作方案修正案

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			
A1. 体制建设项目提案：			
黑山	体制建设（第一阶段，第 1 年和第 2 年）	60,000	60,000
	体制建设小计：	60,000	60,000
A2. 甲基溴项目编制：			
哥伦比亚	甲基溴援助	40,000	40,000
	甲基溴项目编制小计：	40,000	40,000
B 节：建议个别审议的活动			
B1. 氟氯烃投资项目的项目编制：			
阿尔巴尼亚	氟氯烃淘汰管理计划项目编制	244,650	
阿尔及利亚	氟氯烃淘汰管理计划项目编制	392,000	
阿根廷	氟氯烃淘汰管理计划项目编制	214,500	
巴林	氟氯烃淘汰管理计划项目编制	61,000	
波斯尼亚和黑塞哥维那	氟氯烃淘汰管理计划项目编制	244,650	
喀麦隆	氟氯烃淘汰管理计划项目编制	244,650	
中国	氟氯烃淘汰管理计划项目编制	580,250	
克罗地亚	氟氯烃淘汰管理计划项目编制	244,650	
埃及	氟氯烃淘汰管理计划项目编制	643,500	
厄立特里亚	氟氯烃淘汰管理计划项目编制	244,650	
洪都拉斯	氟氯烃淘汰管理计划项目编制	122,326	
印度	氟氯烃淘汰管理计划项目编制	214,500	
印度尼西亚	氟氯烃淘汰管理计划项目编制	214,500	
伊朗伊斯兰共和国	氟氯烃淘汰管理计划项目编制	196,000	
伊拉克	氟氯烃淘汰管理计划项目编制	299,302	
约旦	氟氯烃淘汰管理计划项目编制	244,650	

肯尼亚	氟氯烃淘汰管理计划项目编制	122,326	
朝鲜民主主义人民共和国	氟氯烃淘汰管理计划项目编制	122,326	
科威特	氟氯烃淘汰管理计划项目编制	122,326	
阿拉伯利比亚民众国	氟氯烃淘汰管理计划项目编制	392,000	
前南斯拉夫的马其顿共和国	氟氯烃淘汰管理计划项目编制	244,650	
马达加斯加	氟氯烃淘汰管理计划项目编制	122,326	
马来西亚	氟氯烃淘汰管理计划项目编制	196,000	
墨西哥	氟氯烃淘汰管理计划项目编制	321,750	
摩尔多瓦	氟氯烃淘汰管理计划项目编制	122,326	
黑山	氟氯烃淘汰管理计划项目编制	244,650	
摩洛哥	氟氯烃淘汰管理计划项目编制	244,650	
尼加拉瓜	氟氯烃淘汰管理计划项目编制	244,650	
尼日尔	氟氯烃淘汰管理计划项目编制	122,326	
尼日利亚	氟氯烃淘汰管理计划项目编制	196,000	
阿曼	氟氯烃淘汰管理计划项目编制	190,000	
巴基斯坦	氟氯烃淘汰管理计划项目编制	321,750	
卡塔尔	氟氯烃淘汰管理计划项目编制	127,500	
沙特阿拉伯	氟氯烃淘汰管理计划项目编制	547,000	
塞内加尔	氟氯烃淘汰管理计划项目编制	244,650	
塞尔维亚	氟氯烃淘汰管理计划项目编制	244,650	
南非	氟氯烃淘汰管理计划项目编制	643,500	
苏丹	氟氯烃淘汰管理计划项目编制	392,000	
阿拉伯叙利亚共和国	氟氯烃淘汰管理计划项目编制	392,000	
突尼斯	氟氯烃淘汰管理计划项目编制	244,650	
土耳其	氟氯烃淘汰管理计划项目编制	643,500	
土库曼斯坦	氟氯烃淘汰管理计划项目编制	244,650	
委内瑞拉玻利瓦尔共和国	氟氯烃淘汰管理计划项目编制	643,500	
也门	氟氯烃淘汰管理计划项目编制	122,326	
	氟氯烃投资项目的项目编制小计：	12,225,760	*
B2. 计量吸入器项目编制：			
阿尔及利亚	计量吸入器项目编制	30,000	
阿拉伯叙利亚共和国	计量吸入器项目编制	40,000	
委内瑞拉玻利瓦尔共和国	计量吸入器项目编制	40,000	
	计量吸入器项目编制小计：	110,000	*
B3. 计量吸入器战略：			
朝鲜民主主义人民共和国	计量吸入器过渡战略	30,000	
蒙古	计量吸入器过渡战略	30,000	

计量吸入器过渡战略小计：	60,000	*
A 节和 B 节小计：	12,495,760	100,000
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）：	938,682	8,100
共计：	13,434,442	108,100

* 供个别审议或待决项目

A 节：建议一揽子核准的活动

A1. 延长体制建设

黑山（第一阶段，第 1 年和第 2 年）：（60,000 美元）

项目说明

3. 工发组织提交了一份黑山体制建设项目第一期的申请。上述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. 到目前为止，黑山仅在第五十一次会议上收到了体制建设项目的启动资金。提交的申请是到 2010 年底体制建设项目第一阶段的供资申请。黑山 2006 年消耗臭氧层物质消费量为 15.4 ODP 吨。黑山被认为是一个低消费量国家，因此其体制建设供资应该遵循第 35/57 号决定。

5. 基金秘书处建议按照表 1 所示供资数额一揽子核准黑山体制建设第一阶段的申请。谨建议执行委员会向黑山政府表达下文所示评论：

> 执行委员会审议了黑山申请更新体制建设项目的报告，并赞赏地注意到黑山向臭氧秘书处报告了截至 2007 年底的数据，而且数据低于其 1998 年的平均氟氯化碳履约基准量。 虽然黑山在生产行业中不再需要各类氟氯化碳，但是在完成冷风机替代项目之前，维修行业仍然需要各类氟氯化碳。执行委员会还注意到，在机构体制项目的框架内，黑山在淘汰消耗臭氧层物质的消费量过程中已经迈出了重要的一步；具体来说，即编写国家方案和最终淘汰管理计划、引入和执行立法和行政措施、颁发进出口许可证和建立配额制度、禁止大量进口二手产品、通过举办一次提高认识讲习班初步开展氟氯烃识别活动。在环境规划署的履约援助方案框架内，参加提高公众认识讲习班的有进口商/出口商、维修供应商、海关、统计、职业学校代表和环境

观察员。黑山是欧洲和中亚区域臭氧网的积极成员。执行委员会大力支持黑山削减各类氟氯化碳消费量的努力。因此，执行委员会希望黑山在未来两年里继续实施其国家方案和国家淘汰计划并取得显著成功，从而进一步削减当前的氟氯化碳消费水平。

A2. 甲基溴项目编制

哥伦比亚：甲基溴援助（40,000 美元）

项目说明

6. 工发组织代表哥伦比亚政府提交一份甲基溴技术援助项目的申请。哥伦比亚甲基溴消费的基准消费量为 110 ODP 吨。自 1997 年起，哥伦比亚一直报告甲基溴零消费量。

7. 该项目旨在向可能开始使用甲基溴的新种植者提供有关可用替代技术的信息，以继续保持零消费量。该技术援助还将建立和加强现有法律机制和条例，避免从检疫和装运前消毒处理中使用甲基溴转向农业中控制使用。

基金秘书处的评论

8. 秘书处注意到哥伦比亚是切花的主要种植国和出口国，这项工业使用甲基溴。由于工艺革新，该国一直没有在这种甲基溴的重要应用领域中使用甲基溴。但是哥伦比亚指出，由于花卉种植区域扩大，园艺工业增长，因此如果不进行核查，新种植者可能会带来进口甲基溴来切花的压力。

9. 在同工发组织讨论该项目时，秘书处了解到，哥伦比亚政府意识到了可能出现新使用甲基溴，因此正在寻求援助以杜绝这种现象发生。拟议的活动包括在花卉产量增加的一般区域举办三次讲习班、开始制定一个法律机制来将甲基溴的使用严格限制于仅在检疫和装运前消毒处理中使用、严厉处罚那些试图将甲基溴转向控制使用的人。哥伦比亚政府还计划执行一项体制来严格监控进口水平，其中可能包括为识别用于检疫和装运前消毒处理的甲基溴贴上标签。

10. 哥伦比亚已经收到了第二十六次会议香蕉业使用甲基溴替代技术示范项目的供资。在提交本次申请时，哥伦比亚政府同意这是最后一次为本国甲基溴淘汰供资，该国不会再为相同物质寻求援助。

基金秘书处建议

11. 基金秘书处建议按上述表 1 所示供资数额一揽子核准该计划为哥伦比亚甲基溴淘汰最后一期供资。

B 节：建议个别审议的活动

B1. 氟氯烃投资项目的项目编制

	国家	项目	所需数额（美元）
(a)	阿尔巴尼亚	氟氯烃淘汰管理计划项目编制	244,650
(b)	阿尔及利亚	氟氯烃淘汰管理计划项目编制	392,000
(c)	阿根廷	氟氯烃淘汰管理计划项目编制	214,500
(e)	巴林	氟氯烃淘汰管理计划项目编制	61,000
(f)	波斯尼亚和黑塞哥维那	氟氯烃淘汰管理计划项目编制	244,650
(g)	喀麦隆	氟氯烃淘汰管理计划项目编制	244,650
(h)	中国	氟氯烃淘汰管理计划项目编制	580,250
(i)	克罗地亚	氟氯烃淘汰管理计划项目编制	244,650
(j)	埃及	氟氯烃淘汰管理计划项目编制	643,500
(k)	厄立特里亚	氟氯烃淘汰管理计划项目编制	244,650
(l)	洪都拉斯	氟氯烃淘汰管理计划项目编制	122,326
(m)	印度	氟氯烃淘汰管理计划项目编制	214,500
(n)	印度尼西亚	氟氯烃淘汰管理计划项目编制	214,500
(o)	伊朗伊斯兰共和国	氟氯烃淘汰管理计划项目编制	196,000
(p)	伊拉克	氟氯烃淘汰管理计划项目编制	299,302
(q)	约旦	氟氯烃淘汰管理计划项目编制	244,650
(r)	肯尼亚	氟氯烃淘汰管理计划项目编制	122,326
(s)	朝鲜民主主义人民共和国	氟氯烃淘汰管理计划项目编制	122,326
(t)	科威特	氟氯烃淘汰管理计划项目编制	122,326
(u)	阿拉伯利比亚民众国	氟氯烃淘汰管理计划项目编制	392,000
(v)	前南斯拉夫的马其顿共和国	氟氯烃淘汰管理计划项目编制	244,650
(w)	马达加斯加	氟氯烃淘汰管理计划项目编制	122,326
(x)	马来西亚	氟氯烃淘汰管理计划项目编制	196,000
(y)	墨西哥	氟氯烃淘汰管理计划项目编制	321,750
(z)	摩尔多瓦	氟氯烃淘汰管理计划项目编制	122,326
(aa)	黑山	氟氯烃淘汰管理计划项目编制	244,650
(bb)	摩洛哥	氟氯烃淘汰管理计划项目编制	244,650
(cc)	尼加拉瓜	氟氯烃淘汰管理计划项目编制	244,650
(dd)	尼日尔	氟氯烃淘汰管理计划项目编制	122,326
(ee)	尼日利亚	氟氯烃淘汰管理计划项目编制	196,000
(ff)	阿曼	氟氯烃淘汰管理计划项目编制	190,000
(gg)	巴基斯坦	氟氯烃淘汰管理计划项目编制	321,750
(hh)	卡塔尔	氟氯烃淘汰管理计划项目编制	127,500

(ii)	沙特阿拉伯	氟氯烃淘汰管理计划项目编制	547,000
(jj)	塞内加尔	氟氯烃淘汰管理计划项目编制	244,650
(kk)	塞尔维亚	氟氯烃淘汰管理计划项目编制	244,650
(ll)	南非	氟氯烃淘汰管理计划项目编制	643,500
(mm)	苏丹	氟氯烃淘汰管理计划项目编制	392,000
(nn)	阿拉伯叙利亚共和国	氟氯烃淘汰管理计划项目编制	392,000
(oo)	突尼斯	氟氯烃淘汰管理计划项目编制	244,650
(pp)	土耳其	氟氯烃淘汰管理计划项目编制	643,500
(qq)	土库曼斯坦	氟氯烃淘汰管理计划项目编制	244,650
(rr)	委内瑞拉玻利瓦尔共和国	氟氯烃淘汰管理计划项目编制	643,500
(ss)	也门	氟氯烃淘汰管理计划项目编制	122,326

项目说明

12. 工发组织向本次会议提交了共 44 份氟氯烃淘汰管理计划编制申请，细分如下：

工发组织申请	申请数目
仅工发组织	20
工发组织/环境规划署	15
工发组织/开发计划署	4
工发组织和至少其他两家机构	5
共计	44

13. 在提交中，工发组织提供了一个表格来显示氟氯烃淘汰管理计划编制申请的构成部分及每个相关费用的细分情况。从表中可以看出，工发组织利用低消费量国家分类来决定国家的费用，但是不提供关于寻求供资的国家的氟氯烃消费量的任何信息。

14. 工发组织的费用申请细分如下：

工发组织的申请	费用总计（美元）
对于低消费量国家	244,600
对于中消费量国家	392,000
对于大消费量国家	643,500

15. 相应的活动及其费用如下表所示：

组成	低消费量国家	中	大
	共计	共计	共计
1. 有关利益方项目启动讲习班			
小计	24,500	47,500	94,250
2. 政策/立法/管理和机构框架			
小计	26,250	37,500	48,750
3. 数据采集和调查（消费行业）			
小计	50,750	69,000	110,750
4. 执行氟氯烃淘汰的战略和计划			
小计	59,500	104,500	179,500
5. 费用计算			
小计	10,500	21,000	31,500
6. 项目协调与管理			
小计	48,600	65,000	84,500
7. 氟氯烃淘汰管理计划定稿讲习班			
小计	24,500	47,500	94,250
共计	244,600	392,000	643,500
* 该费用估算并不考虑生产行业的额外费用。 ** 在有两个或两个以上机构合作的国家，考虑到每个机构将要工作的行业以及其所发挥的作用（牵头或合作），这些费用同其他机构共享。			

基金秘书处的评论

16. 在没有商定一致的供资政策，特别是没有氟氯烃相关供资政策情况下，秘书处利用基金到目前为止积攒的经验来解决消耗臭氧层物质淘汰问题。在审查这些申请时，秘书处审议以下几个方面：

(a) 根据第 7 条数据所列清单上的国家的最新氟氯烃消费量；

(b) 呈件中所示氟氯烃淘汰管理计划项目编制的共同点；

(c) 第 54/39 号决定核准的氟氯烃淘汰管理计划指南，以及其中说明的一项氟氯烃淘汰管理计划要点；

(d) 国家方案编制、制冷剂管理计划/最终淘汰管理计划/国家淘汰计划编制初期费用、各国编制氟氯化碳淘汰行业计划的费用以及有氟氯烃生产的国家的个别编制费用；并

(e) 13 个国家初期核准氟氯烃调查的费用。

17. 根据第 54/39 号决定，秘书处也将国家列为两大类：

(a) 仅在维修行业消费氟氯烃的国家（HCFC-22）；以及

(b) 在维修和制造均消费氟氯烃的国家（HCFC-22、HCFC-141b 和其他氟氯烃）。

18. 为了根据执行委员会以前的决定和指南来决定标准费用，秘书处议定，氟氯烃淘汰管理计划的编制供资可以根据第 54/39 号决定分为以下部分：

(a) 政策和立法援助；

(b) 调查氟氯烃使用和分析数据；

(c) 制定和完成全部氟氯烃淘汰管理计划，包括咨询工作；以及

(d) 个别投资项目提案。

19. 秘书处还认为，上述第 18 段中说明的前三个部分是所有国家，不论有无消费量都共同具备的。最后一个部分仅适用于那些在制造中使用氟氯烃的国家。在审议前三个部分时秘书处还注意到，对于一些国家来说这些部分可能已经包含了小型投资项目的一些要点，这些项目可能完成了简单的技术转换而且替代技术众所周知。

20. 工发组织指出，在 44 个提交申请的国家中，有 20 个国家的申请是由工发组织牵头进行的。该机构提供了一份任务清单，说明了其作为牵头机构的职责以及其提交的费用的合理性，本文件载有这些内容。

21. 秘书处注意到，在一些国家中有多个机构并存，而每个机构发挥的具体作用似乎缺乏协调，而且牵头机构的作用并不十分明显。工发组织告知秘书处，在其牵头的国家中，工发组织同其他合作机构开展讨论，并自信能够在相关机构间合理分配费用。工发组织还强调，作为牵头机构其将确保各机构在这些国家中开展的活动不发生重叠。

22. 就中国的情况来说，所有机构提交的中国氟氯烃淘汰管理计划编制申请共计 4,532,995 美元，其中工发组织部分的费用超过 580,000 美元。工发组织证明该申请是针对其他机构按行业分类的职责而同中国政府商定一致的金额，其中将包含国产制冷行业投资项目的项目编制费用。在答复秘书处要求详细说明这笔供资金额时（即个别项目有多少个，将采取何种方式），到编写本文件为止，工发组织尚未向秘书处提供这些信息。

23. 工发组织向秘书处提供了寻求供资的国家类别的预算细目。该细目拟议具体活动及其相应的费用。在同工发组织进行讨论时，秘书处要求工发组织进一步审查这些费用，并重新提交秘书处已审议的方法和费用提案。经过大量讨论，秘书处没有同工发组织就为各国提议的费用，包括中国的费用达成一致。考虑到中国项目的复杂性与规模，秘书处认为需要将编制中国氟氯烃淘汰管理计划的供资申请同其他申请分开而单独审议。

24. 由于各机构提交的编制氟氯烃淘汰管理计划的供资申请的费用范围巨大，秘书处经过上述的细致分析拟议以下费用，如下表所概括：

建议编制氟氯烃淘汰管理计划的费用总表

国家分类	零消费	仅在维修行业消费氟氯烃的国家（仅有HCFC-22）	在维修和制造均消费氟氯烃的国家*（中消费量国家）	在维修和制造均消费氟氯烃的国家*（较大消费量国家）
活动	**预算（美元）**			
1. 氟氯烃许可证制度的政策援助				
法律咨询人	4,000	10,000	15,000	15,000
召开咨询会议，制定指南和规则	4,000	5,000	10,000	10,000
执法信息传播	2,000	5,000	5,000	5,000
小计	**10,000**	**20,000**	**30,000**	**30,000**
2. 调查、数据采集和分析**				
咨询费	5,000	10,000	20,000	40,000
有关利益方咨询会议和报告定稿	5,000	5,000	10,000	10,000
数据采集费用（如需要包括差旅费）	5,000	10,000	25,000	35,000
小计	**15,000**	**25,000**	**55,000**	**85,000**
3. 战略制定与完成				
3 次国家会议（过程开始、最初咨询和最终咨询）	10,000	15,000	20,000	30,000
文件和信息资料（分包合同）	5,000	5,000	5,000	5,000
会议参与者地方差旅开销	10,000	20,000	15,000	15,000
咨询人审查技术，包括气候效益	暂无	暂无	25,000	30,000
小计	**25,000**	**40,000**	**65,000**	**80,000**
总计	**50,000**	**85,000**	**150,000**	**195,000**

* 这些费用是编制氟氯烃淘汰管理计划的标准费用，编制示范和其他投资项目的个别项目的费用另计。

** 各国已经收到的调查供资将相应地调整为低于这些提议的费用。

25. 秘书处同工发组织讨论了为其工作方案修正案中所列的国家的氟氯烃淘汰管理计划项目编制提交的供资金额。尽管到编写本文件为止似乎就提议的方法达成了一致，但是关于费用问题尚未达成一致。

基金秘书处的建议

26. 待定。

B2. 使用氟氯化碳的计量吸入器技术转换项目的项目编制

背景

27. 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。

阿尔及利亚：计量吸入器项目编制（30,000 美元）

项目说明

28. 工发组织代表阿尔及利亚政府提交了一份关于一个计量吸入器转换项目（包括在计量吸入器生产和消费行业制定一个计量吸入器过渡战略，以淘汰氟氯化碳的使用）的编制申请。起初提交的费用为 50,000 美元。该项目将在使用氟氯化碳的计量吸入器行业淘汰 5.9 ODP 吨。

29. 在第五十三次会议上，执行委员会核准了阿尔及利亚的国家消耗臭氧层物质淘汰计划，供资金额为 921,500 美元。该项目包括培训、技术援助和投资活动，并解决所有各类氟氯化碳残余消费问题。计量吸入器行业消耗臭氧层物质的消费量在 2006 年为各类氟氯化碳 5.96 公吨，由于计量吸入器生产中使用各类氟氯化碳较少，因此该问题在当时并未得到解决。引用的另一个原因是计量吸入器的责任和整个制药行业均由卫生部负责管理，而直接负责《蒙特利尔议定书》的政府当局是环境部。

30. 为了支持其提交的项目编制资金并答复第 51/34 号决定，工发组织指出，截至到 2006 年阿尔及利亚政府拥有一家使用氟氯化碳的计量吸入器制造企业，即阿尔及利亚制药实验室，这也是一家完全国有化的公司。虽然这家公司成立于 1991 年，但是仅于 2005 年在意大利凯西制药公司的许可下安装计量吸入器生产线生产沙丁胺醇，2006 年开始全面生产。

31. 阿尔及利亚制药实验室拥有一个生产能力为每年 500 万单位的生产线。该公司仅生产一种产品，即沙丁胺醇，其产品仅够国内消费。由于该公司仅在 2006 年开始生产，以下数据提供了仅 2006 年和 2007 年的年度生产和氟氯化碳使用信息。

年份	单位数量	使用的氟氯化碳（公吨）	
		CFC-11	CFC-12
2006 年	333,000	1.7	2.4
2007 年	480,000	4.3	6.2

32. 该项目数据说明，该公司预计转向氢氟烷烃替代技术，目前的生产线因无法转型而将被完全替代。

33. 阿尔及利亚进口氟氯化碳和不使用氟氯化碳的计量吸入器。在 2007 年其进口总计为 380 万单位。该国进口的不使用氟氯化碳的计量吸入器的数量要比使用氟氯化碳的计量吸入器多。尽管干粉吸入器对于大多数阿尔及利亚人口来说过于昂贵，但是市场上仍有少量流通。阿尔及利亚的详细进口情况作为工发组织工作方案修正案提案的一部分，附于本文之后。

基金秘书处的评论

34. 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氟氯化碳，共计 5.96 ODP 吨。秘书处注意到，虽然提案提到 2007 年核准的国家淘汰计划，但是由于认为计量吸入器的生产是可以忽略的，因此没有将其包括在内。但是在提交国家淘汰计划时，本文指出该国对氟氯化碳计量吸入器的需求大部分可以通过进口来满足，而且阿尔及利亚没有计量吸入器的生产设备。工发组织查明，在 2006 年编制国家淘汰计划时，没有包含计量吸入器的生产，因为阿尔及利亚制药实验室就恰在当年开始生产计量吸入器。秘书处还注意到在阿尔及利亚 2007 年方案执行报告中，该国没有指出计量吸入器使用任何氟氯化碳。履约数据也显示，根据以履约为中心的模式，阿尔及利亚具备零 ODP 吨的残余供资资格。

35. 在审查接受审议的单个公司提交的数据时，秘书处注意到从 2006 年到 2007 年，生产的单位数量显示计量吸入器的产量增加。工发组织告知秘书处，阿尔及利亚制药实验室生产的计量吸入器仅供本国消费，因为该国的进口量多于其生产量。工发组织还警告说慢性阻塞性肺病的发病率在上升，并已经成为一个严重的公众健康问题。但是应该注意的是每年不到 300,000 台计量吸入器的产量比该国的进口量少 8%。

36. 虽然工发组织按第 51/34 号决定的要求提供了关于阿尔及利亚进口使用氟氯化碳的计量吸入器的信息，但是并没有包括产品价格的信息。

37. 在讨论公司的技术转换计划时，秘书处得到的建议是该公司正在试图将其产品设备转换成氢氟烷烃，同时是否能联合供资也已在讨论之中。

38. 秘书处和工发组织讨论了该项目编制所需要的供资。工发组织同意将供资申请从最初申请的 50,000 美元调整为 30,000 美元。

基金秘书处的建议

39. 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。

40. 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，以援助计量吸入器行业，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。

阿拉伯叙利亚共和国：计量吸入器项目编制（40,000 美元）

项目说明

41. 开发计划署代表叙利亚政府，提交了一份项目编制申请，旨在淘汰计量吸入器制造业的氟氯化碳用途。 该项目将在此行业淘汰 50 ODP 吨的各类氟氯化碳使用。

42. 2006 年执行委员会第四十九次会议核准了叙利亚氟氯化碳国家淘汰计划，供资金额为 745,050 美元。该计划解决了所有各类氟氯化碳残余消费问题，到 2005 年残余消费量为 869.7 ODP 吨。此项目包括培训、技术援助和投资活动。该项目并不包括 2005 年计量吸入器行业消耗臭氧层物质 25.71 公吨的消费量，这是因为国家臭氧机构并不了解 Kaspar-Chabani Pharma （又称 K.C. Pharma）计量吸入器生产中的氟氯化碳消费量，而这是由卫生部控制的。

43. 为了支持其提交的项目编制资金并答复第 51/34 号决定，工发组织指出，截至 1998 年，叙利亚政府拥有一家完全国有化的使用氟氯化碳的计量吸入器的制造企业——K.C. Pharma。虽然该公司成立于 1998 年，但是其仅在 1999 年第一次生产计量吸入器。

44. 提交的文件显示，该公司制造七种产品，目前使用氟氯化碳的计量吸入器的生产设备能力为每小时 3,600 罐，一个单一生产线、每天单一转换为每年 850 万罐。但是叙利亚的 KC Pharma 在 2007 年满足的计量吸入器实际需求为每年 200 万计量吸入器。这些产品是在意大利凯西制药公司的许可下进行生产的。

45. 下表提供了过去五年里每一种产品的生产数据：

作品	组成	2003 年	2004 年	2005 年	2006 年	2007 年
Butovent 喷雾	Salbutamol BP 100 mcg/puff	634,000	697,000	780,400	874,000	1,235,000
Clenil Forte 喷雾	Beclomethasone Dipropionate 250 mcg/puff	61,000	67,000	75,000	84,000	99,300
Clenil 喷雾	Beclomethasone Dipropionate 50 mcg/puff	83,000	90,900	101,800	114,000	141,000
Clenil Forte 喷气机	Beclomethasone Dipropionate 250 mcg/puff	3,700	4,100	4,600	5,100	-
Clenil Compositum 喷雾	Beclomethasone Dipropionate 50 mcg/puff Salbutamol BP 100 mcg/puff	59,050	65,000	72,800	81,500	104,700
Asthmatide 50	Salmeterol 25 mcg/puff Fluticasone Propionate 50 mcg/puff		4,100	8,200	6,400	12,400
Asthmatide 125	Salmeterol 25 mcg/puff Fluticasone Propionate 125 mcg/puff		11,600	25,400	32,600	49,900
Asthmatide 250	Salmeterol 25 mcg/puff Fluticasone Propionate 250 mcg/puff		7,400	16,900	23,800	36,200
Flusone 44	Fluticasone Propionate 50 mcg/puff	6,100	4,700	5,500	7,100	9,500
Flusone 110	Fluticasone Propionate 125 mcg/puff	7,500	11,700	7,600	14,200	16,800
Flusone 220	Fluticasone Propionate 250 mcg/puff	4,900	7,500	6,800	10,800	12,700
Asthmerol	Salmeterol 25 mcg/puff	14,600	32,500	37,800	39,100	46,200
共计		**873,850**	**1,003,500**	**1,142,800**	**1,292,600**	**1,763,700**

46. 这一项目数据指出，公司考虑转向氢氟烷烃替代品，而目前的生产线应该被完全更换，因为它已经无法进行改型。

47. 只有两种类型的基于干粉吸入器的吸入器（沙美特罗替卡松和沙丁胺醇）被允许进口到叙利亚。2007 年，该国总共进口了 3,500 台这两种产品。除了提到的两份文件，叙利

亚没有提供关于进口计量吸入器的数据。文件指出，其他进口是禁止的，尽管认为可能存在氟氯化碳计量吸入器的非法进口和其他氟氯化碳计量吸入器进入该国。

基金秘书处的评论

48. 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 51.7 ODP 吨的氟氯化碳。秘书处指出，虽然提案述及了 2006 年核准的国家淘汰计划，但是它没有包括计量吸入器的生产，因为在项目编制时由于责任划分不一（如制药行业属卫生部管），没有对生产进行确认。秘书处还指出，在 2007 年提交的国家方案执行情况报告中，叙利亚报告计量吸入器行业的消费量为 51.7 ODP 吨。根据以履约为主导的模式，数据表明，叙利亚剩余的供资资格为零 ODP 吨。

49. 在审查针对正在审议的公司所提交的数据时，秘书处指出，如上表所示，生产量在 2003 年到 2007 年之间几乎翻了一番。工发组织告知秘书处，该国有近 5-6%的人口使用计量吸入器用于治疗哮喘。该公司还曾向伊拉克出口其产品。然而，最新的规定只允许氢氟烷烃计量吸入器进入该国，因此这一出口已经停止。从所提供的数据中无法得知出口的次数或数量。

50. 工发组织没有提供第 51/34 号决定所要求的该公司过去五年里使用氟氯化碳趋势的数据。工发组织指出的是，2007 年，为生产计量吸入器而进口约 50 ODP 吨的氟氯化碳。秘书处被告知，由于必须经过卫生部，同时又被认为是一种制药成分，数据的获得十分困难，因此结关也通过卫生部进行。工发组织还建议，该公司目前正在申请许可证与登记，以便开始布替耐德氟氯化碳计量吸入器的生产。

51. 在讨论该公司的转产计划时，秘书处获悉，该公司正在考虑将其生产设施转为氢氟烷烃，联合筹资的可能性已经得到讨论。在阐述该进程的两年期完工时，工发组织回复说，这一时期只是针对两种最重要的计量吸入器：沙丁胺醇和丙酸倍氯米松。其他制剂将在项目核准之后 6-12 个月内完成，因为关于其转厂的工作已经开始。工发组织还指出，如果获得核准，该公司将愿意考虑对转厂费用进行联合筹资。

基金秘书处的建议

52. 鉴于上述评论意见，秘书处的审查表明，所提供的文件并没有满足第 51/34 号决定的全部要求，因此无法推荐这一项目获得执行委员会的经费。谨建议执行委员会根据上述评论意见审议对阿拉伯叙利亚共和国计量吸入器项目编制的申请。

委内瑞拉玻利瓦尔共和国：计量吸入器项目编制（40,000 美元）

项目说明

53. 工发组织代表委内瑞拉政府提交关于编制计量吸入器转厂项目的申请，包括一项计

量吸入器过渡时期战略，以淘汰在计量吸入器生产和消费行业中的对氟氯化碳的使用。最初提交的费用为 50,000 美元。这一项目将淘汰计量吸入器生产行业的 29.6 ODP 吨氟氯化碳。

54. 在第四十二次会议上，执行委员会核准了委内瑞拉旨在淘汰该国 2,032 ODP 吨氟氯化碳的国家氟氯化碳淘汰计划。工发组织指出，国家淘汰计划中没有对计量吸入器行业的 20 ODP 吨或更多氟氯化碳消费量进行适当解释，因为消费量没有得到正确的记录，因此申请了这一经费。

55. 为支持其对项目编制经费申请并回复第 51/34 号决定，工发组织指出，截至 1991 年，委内瑞拉政府拥有一家氟氯化碳计量吸入器制造企业 Laboratoris L.O. Oftalmi, CA，这是一家 100%的国有企业。该公司于 1991 年开始生产计量吸入器，并满足了全国保健服务的 80%。剩余的 20%进入了国家的自由市场。该公司不出口氟氯化碳计量吸入器。

56. Oftalmi 的实际生产量为每天 8 小时制下每天 200 万台。由于没有关于生产线数量的资料，于是假定这一资料只是一条生产线的资料。该公司生产四种产品，关于这些产品的数据概述如下表所示：

产品	2003 年	2004 年	2005 年	2006 年	2007 年
Venticort	261,086	363,514	368,640	463,112	785,419
Duovent (*)	63,220	66,910	45,315	0	0
Cromospray (*)	55,949	58,425	8,014	0	0
沙丁胺醇	596,111	593,054	732,649	555,787	546,296
Beclomax	294,378	325,415	319,616	141,663	423,680
Budecort	281,563	286,112	273,487	147,106	193,622
共计	**1,552,307**	**1,693,430**	**1,747,721**	**1,307,668**	**1,949,017**

(*) 这些产品已于 2004 年 5 月停止生产。

57. 氟氯化碳消费趋势如下表所示：

年份	CFC-11	CFC-12	氟氯化碳消费总量（公斤）
2003 年	8,450	12,266	20,716
2004 年	9,904	15,055	24,959
2005 年	11,714	16,391	28,105
2006 年	8,989	13,864	22,853
2007 年	12,106	17,454	29,560
共计	**51,163**	**75,030**	**126,193**

58. 该项目数据指出，该公司考虑转向氢氟烷烃的替代品，而目前的生产线将必须完全

得到更换，因为它不能进行改型。

59. 委内瑞拉既进口氟氯化碳，也进口不使用氟氯化碳的计量吸入器。文件指出，氟氯化碳计量吸入器仍然占据着进口市场。工发组织根据所使用的推进剂概述了过去三年里的进口数据，如下表所示：

	2005年	2006年	2007年
氟氯化碳计量吸入器	761,300	923,000	1,007,200
干粉吸入器	369,700	470,200	561,400
氢氟烷烃计量吸入器	592,700	771,300	854,000
共计	**1,723,700**	**2,164,500**	**2,422,600**

基金秘书处的评论

60. 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 29.6 ODP 吨的氟氯化碳。秘书处指出，虽然提案述及了 2004 年核准的国家淘汰计划，但是它没有包括计量吸入器生产中氟氯化碳的使用量，因为在项目编制时没有对使用氟氯化碳的情况进行确认，因此没有包括在国家淘汰计划中。秘书处还指出，在 2007 年的国家方案执行报告中，委内瑞拉报告，在计量吸入器行业的消费量为 29.6 ODP 吨。根据以履约为主导的模式，数据表明，委内瑞拉剩余的供资资格为零 ODP 吨。

61. 在审查为该公司提交的数据时，秘书处指出，生产量稳步增加。特别是，自 2003 年以来一直增产的沙丁胺醇似乎在 2006 年和 2007 年有所下降。这可能是由于对这一药物的进口所致。工发组织还告知秘书处，该公司主要为患慢性阻塞性肺病的人口提供支付得起的计量吸入器。

62. 在讨论该公司的转厂计划时，秘书处询问 Laboratorios L.O. Oftalmi, C.A.公司和其任何其他制药公司之间的特许安排和/或技术援助合同情况，特别是进行转厂的技术转让。秘书处被告知，Oftalmi 具有可以处理这些问题的专门知识，因为它是委内瑞拉唯一的计量吸入器制造商。工发组织还告知秘书处，该公司正在考虑将其生产设施转为氢氟烷烃，并已经与该公司进行了关于联合筹资可能性的讨论，因为该公司也同意对转厂的费用进行分担的想法。工发组织还强调，最后项目将包括一份全面的计量吸入器过渡战略。

63. 在讨论项目的费用时，秘书处请工发组织重新考察其费用，因为其相对于消费量过高。工发组织同意将项目编制的供资申请削减至 40,000 美元。

基金秘书处的建议

64. 鉴于上述评论，秘书的审查结果表明，提供的文件不符合第 51/34 号决定的全部要求，并且建议此项目不能获得执行委员会的供资。谨建议执行委员会根据上述评论审议向委内瑞拉计量吸入器项目编制工作供资的申请。

B3. 计量吸入器战略

背景

65. 执行委员会在第五十一次会议的第 51/34（d）号决定中特别商定“依照第 45/54 号决定逐案审议没有计量吸入器生产设施的第 5 条缔约方要求编制过渡到无氟氯化碳计量吸入器的战略的请求，但缔约方必须提交最近三年的以下资料，充分显示和说明需要这一战略：

(a) 氟氯化碳和无氟氯化碳计量吸入器及干粉吸入器：在缔约方销售或运销的数量，按其活性成分、商标/厂家和来源分列；

(b) 无氟氯化碳计量吸入器及干粉吸入器：缔约方国内核准、批注销售和/或推出的日期；

(c) 氟氯化碳和无氟氯化碳计量吸入器及干粉吸入器：估计成本，按活性成分和来源分列。”

朝鲜民主主义人民共和国：计量吸入器过渡战略（30,000 美元）

项目说明

66. 工发组织代表朝鲜民主主义人民共和国（朝鲜）政府为计量吸入器过渡战略的编制提交了申请，以淘汰在计量吸入器消费行业中使用的氟氯化碳。随同资料一起提供的数据表明，朝鲜没有生产氟氯化碳计量吸入器。数据还显示，氟氯化碳和无氟氯化碳计量吸入器的进口都出现增长趋势。现有的数据表明，2005 年和 2007 年分别进口了 200 多万件此类医疗产品，但 2007 年降至 190 万件。进口的主要来源国为俄罗斯。

67. 朝鲜政府及其卫生局还特别关注计量吸入器次行业，原因是统计数据显示，该国慢性阻塞性肺病和哮喘病的发病率超过了 900,000 例。因此，迫切需要确保稳定供应可负担的计量吸入器，以满足这些病人的需要。为编制计量吸入器过渡战略而申请的供资将为氟氯化碳计量吸入器替代品进口制订一项明确的时间表。由于朝鲜是中央计划经济，并且国家政府全力支持这一请求，因此预计将会如期执行该过渡战略。同时还将起草所需条例，促进和支持这些产品，并起草一项方案，提高医生的认识和患者对氟氯化碳计量吸入器替代品的接受程度，并对计量吸入器的进口情况进行监测。

68. 根据其提交的资料和第 51/34 号决定，工发组织表示，关于朝鲜计量吸入器的供应及其无氟氯化碳替代品的状况可简要概括如下：

(a) 虽然可获得氟氯化碳计量吸入器，但没有无氟氯化碳替代品，不论是氢氟碳化物产品还是干粉吸入器；

(b) 2005 年至 2007 年，氟氯化碳计量吸入器的进口量略微下降。2005、2006 和 2007 年的进口量分别为 2,311,600 件、2,213,440 件和 1,964,050 件；并且

(c) 最近三年的价格保持平稳。

69. 下表概述了最近三年朝鲜计量吸入器的进口情况：

计量吸入器商标名称	活性成分	每件计量吸入器的费用，美元	推进剂	进口的计量吸入器件数/年		
				2005 年	2006 年	2007 年
Ventalex	沙丁胺醇	2	CFC	2,126,000	2,013,400	1,867,400
Beclex	二丙酸倍氯米松	2	CFC	185,600	200,040	196,650
			共计	2,313,600	2,213,440	2,064,050

基金秘书处的评论

70. 提交了项目编制申请以便使朝鲜向无氟氯化碳计量吸入器的过渡能够顺利进行，从而淘汰计量吸入器行业中的氟氯化碳消费量。在审查提交的数据和资料时，秘书处注意到该国仅进口两种产品，即沙丁胺醇（占进口量的 90%以上）和二丙酸倍氯米松。这些产品均来自一个国家，俄罗斯联邦，并且替代品－氟氯烷烃-沙丁胺醇和氟氯烷烃-二丙酸倍氯米松在全世界范围内得到了很好的开发和利用。

71. 鉴于上文所述，秘书处认为朝鲜氟氯化碳计量吸入器过渡战略的请求不合理。

基金秘书处的建议

72. 根据上述评论，秘书处建议不向朝鲜编制氟氯化碳计量吸入器过渡战略提供申请的供资。

蒙古：计量吸入器过渡战略（30,000 美元）

项目说明

73. 工发组织代表蒙古政府为计量吸入器过渡战略的编制提交了申请，以淘汰在计量吸入器消费行业中使用的氟氯化碳。随同资料一起提交的数据显示，蒙古没有生产氟氯化碳计量吸入器，并且该国仅从俄罗斯联邦进口一种产品，即沙丁胺醇。

74. 蒙古政府及其卫生局还特别关注计量吸入器次行业，原因是统计数据显示，该国的慢性阻塞性肺病和哮喘病的发病率已上升，因此迫切需要确保稳定供应可负担的计量吸入

器，以满足这些病人的需要。为编制计量吸入器过渡战略而申请的供资将为氟氯化碳计量吸入器替代品进口制定一项明确的时间表。 由于蒙古政府是中央计划经济，并且国家政府全力支持这一请求，因此预计将会如期执行该过渡战略。同时还将起草所需条例，促进和支持这些产品，并起草一项方案，提高医生的认识和患者对氟氯化碳计量吸入器替代品的接受程度，并对计量吸入器的进口情况进行监测。

75. 根据其提交的资料和第 51/34 号决定，工发组织通过下表，概述了最近三年蒙古计量吸入器的进口情况：

活性成分	生产商	推进剂	进口的计量吸入器件数/年		
			2003 年	2004 年	2005 年
沙丁胺醇,气雾剂-12 毫升	Moschimfarm，俄罗斯	氟氯化碳		8,538	6,480
沙丁胺醇,气雾剂-12 毫升	Altaivitamin，俄罗斯	氟氯化碳	10,000		

基金秘书处的评论

76. 提交了项目编制申请以便使蒙古向无氟氯化碳计量吸入器的过渡能够顺利进行，从而淘汰各类氟氯化碳。提案提供的计量吸入器行业方面的资料非常有限，仅载有 2003 年至 2005 年的进口数据，未涉及 2006 年和 2007 年。同样也没有提供资料，说明地方药品局核准的日期，以及批准蒙古销售和推出的日期。

77. 提供的资料显示，该国进口的计量吸入器数量很少（2005 年不足 6,500 件）；沙丁胺醇是仅有的活性成分，并且所有进口均来自俄罗斯联邦。还注意到，氟氯烷烃-沙丁胺醇在全世界范围内得到了很好的开发和利用。

78. 在进一步阐述该申请时，工发组织承认，就蒙古提供的资料和数据确实较少。但它们主张，尽管需以氢氟烷烃计量吸入器替代的氟氯化碳计量吸入器数量很少，但仍需实施一项宣传方案，对医生、药剂师和病人进行教育。工发组织强调，过渡战略可向蒙古的计量吸入器市场提供一项分析，并协助针对该国氟氯化碳计量吸入器的总体淘汰工作设定一个最后期限。在这方面，卫生部、保健提供方、医生、药剂师和护理工作人员以及所有与此相关的行业应通力协作。该战略还将提供一份文件，指导执业医师和病人了解为何需要进行过渡，以及如何顺利完成过渡，同时还强调采用替代品药物会带来同样的治疗效果。

79. 然而，根据第 51/34 号决定的各项要求，秘书处认为蒙古氟氯化碳计量吸入器过渡战略的请求不完全合理。

基金秘书处的建议

80. 根据上述评论，秘书处建议不核准为蒙古编制氟氯化碳计量吸入器过渡战略申请的供资。

附件一

体制建设项目提案

蒙古：延长体制建设

项目摘要和国家概况	
执行机构：	工发组织
以前核准的体制建设供资数额（美元）： 体制建设启动：2007 年 3 月 共计	 30,000 30,000
延长所需的数额（第一阶段- 第 1 年和第 2 年）（美元）：	60,000
第一阶段建议核准数额（第 1 年和第 2 年）（美元）：	60,000
机构支助费用（美元）：	4,500
多边基金体制建设第一阶段总费用（第 1 年和第 2 年）（美元）：	64,500
由于体制建设第一阶段（第 1 年和第 2 年）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：	2007 年 11 月
国家方案报告的消耗臭氧层物质消费量（2006 年）（ODP 吨）：	14.1
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（甲基氯仿）（1998-2000 年平均数） (e) 附件 E（甲基溴）（1995-1998 年平均数）	 104.9 2.3 1.1 0 0
根据第 7 条报告的消耗臭氧层物质最新消费量（2006 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（甲基氯仿） (e) 附件 E（甲基溴） (f) 附件 C 第一类物质（氟氯烃） 共计	 14.0 0 0.1 0 0 1.3 15.4
报告的国家方案执行数据的年份：	2007 年
核准的项目供资数额（美元）：	245,000
支付的数额（截至 2008 年 5 月）（美元）：	19,973
将淘汰的消耗臭氧层物质（ODP 吨）：	3.0
已淘汰的消耗臭氧层物质（截至 2008 年 5 月）（ODP 吨）：	-

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：	175,000
(b)	体制建设：	30,000
(c)	项目编制、技术援助、培训和其他非投资项目：	40,000
	共计：	245,000

进度报告

2. 执行委员会第五十一次会议核准提供经费，启动体制建设项目，从而允许该国设立国家臭氧办公室，并协调为编制国家方案/最终淘汰管理计划而开展的各项活动。国家臭氧机构隶属旅游和环境部，是《蒙特利尔议定书》活动的协调点。臭氧机构与旅游和环境部以及该部法律服务部门共同协调项目目标的履行情况，后者编写了立法提案并提交至政府和议会，供其核准。与《蒙特利尔议定书》相关的活动方案是蒙古采取管制及节约型方式淘汰消耗臭氧层物质消费量承诺的一部分。2006 年，蒙古加入了《蒙特利尔议定书》；早在 2004 年其就设立了许可证制度，并禁止大量进口二手产品，自 2007 年以来，它根据配额制度颁发了许可证。此外，该国开展了一些公共宣传活动。臭氧干事还参加了环境规划署和工发组织召开的各次技术会议。在识别氟氯烃方面，蒙古还采取了初步行动，并在其国家方案报告中报告了氟氯烃数据。

行动计划

3. 国家臭氧机构被视为消耗臭氧层物质管理结构的核心，并作为一个专门机构而设立，用于执行国家方案行动计划规定的消耗臭氧层物质淘汰战略，并采取后续行动。通过与环境部及该部门法律服务部门（其编写了立法提案并提交至政府和议会，供其核准）密切合作，得以确保臭氧机构与高级决策者能定期取得联系。《蒙特利尔议定书》事项是该部年度计划的一部分，此外该部向政府提交的报告也载有执行《蒙特利尔议定书》的进展情况。蒙古与欧洲联盟国家综合计划将纳入臭氧问题。今后几年的主要目标是执行最终淘汰管理计划，编制氟氯烃调查报告和氟氯烃淘汰管理计划，对海关官员进行培训，并制定有效的回收和再循环计划。

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Explanatory Note on the Costing of HPMP Preparatory Projects

1. The current HCFC consumption figures reported by the countries in previous years are in many cases misleading and inaccurate.
    a. On the basis of the level of development and size of industry of several countries and taking into consideration UNIDO's earlier experience working with them, we believe that some countries reported unrealistically high HCFC consumption data, whereas others reported very low.
    b. We also observed that in many countries HCFCs were phased in as alternatives to CFCs, however, some of these countries still report zero consumption of HCFCs.
    c. Countries, which reported zero consumption, would need more assistance in data reporting. We believe that such are still not ready yet to report reliable figures on HCFC consumption as having zero consumption in a country is practically not possible at the present time.
    d. The actual HCFC consumption data will be verified through the HPMP.
2. Since in many cases the currently available HCFC consumption data do not reflect the real consumption in the country they cannot be considered as the only basis for the calculation or categorization of countries at this point of time and it cannot be used as a reliable tool for determination of funding of the HPMP preparation.
3. When calculating funding requirements for HPMP preparation, costs for the preparation of individual investment projects should also be considered, since the 1st stage of the HPMP in countries with HCFC consumption in manufacturing sectors must include enterprise level investment projects as well.
4. The inflation during the last 15 years as well as the strong depreciation in the value of the US$ and the fast growing air fares should also be accounted for.
5. In addition, the geographical location, complexity and size of a country as well as its industrial structure are parameters that UNIDO considered in drawing the estimated figures.
6. It is also to be noted that in countries where we have dealt only with the servicing sector in the phase out of CFCs, it cannot be ruled out that HCFCs are being used in the manufacturing sector as well. So, for countries we see a likelihood of HCFC manufacturing uses we have to budget some funds in the preparation of the HPMP to avoid to the extent possible future additional requests for updates to accommodate the manufacturing sectors.
7. Requirements for the preparation of the HPMPs as per decision 54/39 are much more extensive than the requirements for the preparation of the CP/RMP/NPP or TPMP. Furthermore, TPMPs and NPPs in most cases dealt only with the 15% remaining consumption, at a time when we have already had clearer information about the situation of the different sectors in the Country. RMPs dealt with the refrigeration-servicing sub-sector only, while HPMP will have to review several sectors.
8. HCFC replacement technologies are not yet well established in Article 5 Countries, which creates an additional difficulty.
9. The stakeholders for HCFC phase-out are in many cases different from those, which were involved in the phase out of CFCs except for the second-stage conversion in the manufacturing sector. Thus, we never dealt with
    a. Enterprises established after 1995,
    b. Stakeholders in the sectors of air conditioning, part of commercial and industrial refrigeration sector, many XPS producers etc…
10. The task of the HPMP preparation is not limited to collection of additional data only but it also requires dealing with the selection of alternatives, technology transfer, priority setting, budgeting, strategy preparation, etc… According to the HPMP guidelines, the HPMP should include analysis and information about the availability of alternatives, selection of alternative technologies, ICC and IOC calculations, evaluation of climate change impact etc., as well as cost scenarios for the phase out. It is our understanding also that the HPMP should already include proposals for projects (investment and non-investment) to enable the Country's compliance with the 2013 and 2015 phase out control measures. The calculation of ICC and IOC for the manufacturing enterprises has to be enterprise specific especially in the initial stage. This needs to be budgeted – one time preparatory fund compensation for the sector is not sufficient as there is a need to design several enterprise level interventions. Without the said detailed information and justifications related to the investment projects difficulties will arise at the time of the review and approval process.

11. The HPMP will be a performance-based document while the CP was not. The reliability of the HPMP document should be far higher.
12. The regional network experts referred to by the Secretariat can be used in limited extent. There is a lack of knowledge and experience on alternatives to HCFCs in Article 5 Countries therefore international expertise will be required to work along with national experts who will have to prepare in-depth on site surveys, data collection etc. Costs for both expert categories should be accounted for.
13. According to the HPMP preparation guidelines, through the preparation and implementation of the HPMP, the agencies should *"Assisting the country in establishing a licensing system including a comprehensive monitoring and control system. Countries should be encouraged to include or revise their current licensing systems to accommodate the adjustments adopted at the XIVth Meeting of the Parties during the development of the overall HPMPs. As the funding for the full HPMP implementation is likely to be provided only subsequent to an update of current regulations to include HCFCs, the Executive Committee could require the availability of an appropriate licensing system for HCFCs to be in place as a condition for the approval of funding for HPMP implementation, consistent with current guidelines for TPMPs."* Therefore, we understand that even in cases where the licensing of HCFC is in place, the Countries are required to adjust that to the new phase out schedules, take policy measures to curb import of HCFC containing equipment and that the Agencies need to assist the countries in setting up a proper monitoring and control system. This is a very important aspect since it will be a condition for future funding related to the HPMP implementation.
14. According to our analysis and findings, the average level of PRP-funding approved by the Multilateral Fund in all countries in the various categories (considering the preparatory assistance funds approved for the preparation of projects in the foam, refrigeration and solvent sectors but excluding the halon, fumigation, aerosol and production sectors) was around US$ 350,000. The figure of US$ 100,000 quoted by the Secretariat is not a realistic one and cannot be used for the HPMP preparation considering the level of information to be collected and the current price and currency situation mentioned earlier. In addition, the funds approved for preparing individual projects should also be taken into account.
15. We would like to underline that the level of details required by the HPMP guidelines is much more elaborate than the data collected for the surveys approved earlier by the ExCom. In fact the surveys are only a part of one component of the overall plan.
16. UNIDO, when preparing its first submission evaluated the countries, based on their reported HCFC consumption and also based on their size, geographical location, industrial development and other parameters. All these factors determine the likely magnitude of resources needed to prepare the HPMP. So, the governing criteria have been the <u>expected real cost of preparation of the HPMP</u>. The smaller and simpler cases were put into the first category.
17. We did not calculate the cost of production closure projects. Maybe a separate category of countries with servicing, manufacturing and production needs should be considered.
18. In the Work Programme Amendment submitted earlier, UNIDO provided a detailed cost breakdown.
19. Based on our telephone conference we have reformulated our earlier submission with an attempt to follow the logic the Secretariat requested us to look at:
    a. We took into consideration the more detailed categorization of countries as presented by the Secretariat and classified our counterparts according to these categories.
    b. We have also grouped the activities in similar categories as recommended by the Secretariat; however an additional category of activities was added, which relates to coordination, management and monitoring of the HPMP preparation activities.
    c. We included average costing for each group of activities in each category of countries.
20. Following the approach directed by the Secretariat, we were able to reduce the total budget of our submission. The results are summarized in the two tables attached.

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	Cost	#	Cost	#	cost	#	cost	#	cost	#	cost
Policy	National expert (US$ 2,000/w.m.)	2,000	2	4,000	2	4,000	4	8,000	2	4,000	4	8,000	7	14,000	10	20,000
	International expert (US$ US$15,000/w.m.), incl. international travel	15,000	1.00	15,000	1.00	15,000	1	15,000	1.00	15,000	1	15,000	2.00	30,000	2	30,000
	Stakeholder consultation workshops (US$ 25,000/workshop)	25,000	1	25,000	1	25,000	1	25,000	1	25,000	1	25,000	2	50,000	3	75,000
	Sub-total			**44,000**		**44,000**		**48,000**		**44,000**		**48,000**		**94,000**		**125,000**
National, sectoral and enterprise level data collection	National experts undertaking national, sectoral and enterprise level consumption data (US$ 2,000/w.m.)	2,000	5	10,000	5	10,000	10	20,000	5	10,000	10	20,000	18	36,000	24	48,000
	Local travel	5,000	1	5,000	2	10,000	3	15,000	2	10,000	3	15,000	4	20,000	6	30,000
	International experts to analyze the data collected (US$ US$15,000/w.m.), incl. international travel	15,000	1	15,000	1.00	15,000	1	15,000	1.00	15,000	1	15,000	1	15,000	2	30,000
	Sub-total			**30,000**		**35,000**		**50,000**		**35,000**		**50,000**		**71,000**		**108,000**

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	Cost	#	Cost	#	cost	#	cost	#	cost	#	cost
Strategy Development	National expert (sectoral) to investigate the availability of alternatives and assist in the development of phase out scenarios (US$ 2,000/w.m.)	2,000	2	4,000	4	8,000	6	12,000	4	8,000	6	12,000	7	14,000	10	20,000
	International experts (sectoral) advise on the selection of alternatives and develop phase out scenarios (US$ US$15,000/w.m.), incl. international travel	15,000	1	15,000	1	15,000	1.00	15,000	1	15,000	2.00	30,000	2	30,000	3	45,000
	Stakeholder consultation workshops	25,000	1	25,000	1	25,000	1	25,000	1	25,000	1	25,000	2	50,000	3	75,000
	Sub-total			**44,000**		**48,000**		**52,000**		**48,000**		**67,000**		**94,000**		**140,000**

Consumption range (in ODP tonnes)	Activity	Per unit cost	Zero Consumption		Countries with servicing consumption only				Countries with consumption in both servicing and manufacturing **							
					Below 6		6 - 100		Below 6		6 - 100		101 to 500		501 to 1200	
			#	Cost	#	**Cost**	**#**	**Cost**	#	cost	#	cost	#	cost	#	cost
Investment and TAS project preparation	National expert to collect all enterprise level baseline data required for project preparation (US$ 2,000/w.m.)	2,000	2	4,000	4	8,000	6	12,000	6	12,000	8	16,000	11	22,000	14	28,000
	International expert to visit selected enterprises and prepare phase out projects (US$ US$15,000/w.m.), incl. international travel	15,000	**1**	15,000	2	30,000	3	45,000	2	30,000	3	45,000	3	45,000	6	90,000
	Sub-total			**19,000**		**38,000**		**57,000**		**42,000**		**61,000**		**67,000**		**118,000**
Sub-total for all components				**137,000**		**165,000**		**207,000**		**169,000**		**226,000**		**326,000**		**491,000**
Management, coordination and monitoring of the HPMP preparation	Project coordinator, database creation, telecommunication, office costs, incidentals	**20% of overall HPMP cost**		**27,400**		**33,000**		**41,400**		**33,800**		**45,200**		**65,200**		**98,200**
TOTAL Cost of HPMP preparation				**164,400**		**198,000**		**248,400**		**202,800**		**271,200**		**391,200**		**589,200**

Country	Consumption	Total Funding Request, US$	UNIDO funding request, US$	Agencies involved
Zero Consumption				
Albania	0	164,400	164,400	UNIDO single
Korea DPR	0	164,400	164,400	UNIDO single
Sudan	0	164,400	164,400	UNIDO single
	sub-total	493,200	**493,200**	
Servicing Consumption Only				
below 6				
Eritrea	1	198,000	198,000	UNIDO single
Macedonia	2.4	198,000	198,000	UNIDO single
Madagascar	2.6	198,000	70,000	UNEP lead
Nicaragua	3.4	198,000	198,000	UNIDO single
Niger	0.8	198,000	128,000	UNEP cooperating
sub-total		990,000	**792,000**	
6 to 100				
Servicing and Manufacturing				
Below 6				
Moldova	0.7	202,800	80,000	UNDP lead
Montenegro	1.3	202,800	202,800	UNIDO single
Turkmenistan	5.6	202,800	202,800	UNIDO single
	Sub-total	608,400	**485,600**	
6 to 100				
Algeria	6.6	271,200	271,200	UNIDO single
Bahrain	28.7	271,200	100,000	UNEP lead
Bosnia and Herzegovina	10	271,200	271,200	UNIDO single
Cameroon	10.2	271,200	271,200	UNIDO single
Croatia	10.4	271,200	271,200	UNIDO single
Honduras	12.2	271,200	148,000	UNEP cooperating
Jordan	55.7	271,200	271,200	UNIDO single
Kenya	42.5	271,200	100,000	UNEP lead
Libya	28.5	271,200	271,200	UNIDO single
Morocco	49.8	271,200	271,200	UNIDO single
Nigeria	35.8	271,200	100,000	UNDP lead
Oman	32.2	271,200	148,000	UNEP cooperating
Pakistan	65.5	271,200	100,000	WB lead
Qatar	15	271,200	148,000	UNEP cooperating
Senegal	9.6	271,200	271,200	UNIDO single
Serbia	9	271,200	271,200	UNIDO single
Syria	49	271,200	271,200	UNIDO single
Tunisia	31	271,200	271,200	UNIDO single
		4,881,600	**3,827,200**	
101 to 500				
Argentina	248	391,200	120,000	UNDP lead
Egypt	256	391,200	391,200	UNIDO single
Indonesia	299.9	391,200	80,000	UNEP lead, WB cooperating

Country	Consumption	Total Funding Request, US$	UNIDO funding request, US$	Agencies involved
Iran	166.5	391,200	80,000	UNDP lead, UNEP & GTZ cooperating
Kuwait	286.3	391,200	180,000	UNEP lead
Malaysia	383	391,200	120,000	UNDP lead
South Africa	222	391,200	391,200	UNIDO single
Venezuela	125	391,200	391,200	UNIDO single
Yemen	102.7	391,200	180,000	UNEP lead
		3,520,800	**1,933,600**	
501 to 1200				
India	592.5	589,200	100,000	UNDP lead, UNEP and GTZ cooperating
Mexico	1425	589,200	350,000	UNDP cooperating
Saudi Arabia	736	589,200	400,000	UNEP cooperating
Turkey	850	589,200	589,200	UNIDO single
		2,356,800	**1,439,200**	
TOTAL		12,850,800	**8,970,800**	
China			582,500	
GRAND TOTAL			**9,553,300**	

Description of the Role and Responsibility of a Lead Agency for the Preparation of an HPMP

Paragraphs 55 to 58 of document 54/53 containing the draft guidelines for the preparation of HCFC phase out management plans (HPMPs) outline the requirement for project coordination and management including monitoring and evaluation during the preparation of an HPMP. It requires Countries to

- Describe the management structure for the implementation of the HPMP
- Establish a project management unit.
- Assign the roles to be assumed by government bodies, industry bodies, academic institutions and consultants.
- Designate a government entity to which the management body would be held accountable

In defining the lead implementing agency's roles and responsibilities, UNIDO carefully considered the requirements stipulated in the guidelines for the preparation of the HPMPs and specifically those relating to the project coordination and management. Accordingly, these can be summarized below:

The Lead IA in close cooperation with the Government will be responsible for a range of activities as follows:

- Draw up the modality, organizational structure and time schedule of the preparation of HPMP.
- Prepare questionnaires for data survey.
- Assist the Country in developing a consistent long-term strategy that provides an overall direction and includes a list of critical actions and performance indicators to achieve the HCFC phase-out targets.
- Provide assistance in formulation of policy, capacity building and management issues governing HCFC consumption, import and production in the country. Assist the Country in preparing a strategy for the management of HCFC supply and demand including formulation and timely adoption of quota system for HCFCs and regulating import of HCFC containing goods.
- Support and advise the country in collection, compilation and analysis of data related to national level HCFC consumption;
- Assist the Country in elaborating a concrete prioritized approach to implement stage one of the HPMP describing specifically and comprehensively how the Country intends to meet the initial HCFC control measures in 2013 and 2015.
- Assist in formulation of strategic and policy level technical support activities related to screening of and establishing criteria for the selection of alternative substances, technologies and modalities of technology transfer as required.
- Implement all enterprise and sectoral level data collection, survey and program formulation activities as well as selection of alternative substances, technologies and formulation of investment projects in the sector(s) assigned to the Lead IA.
- Coordinate and facilitate the enterprise and sectoral level data collection, survey and program/project formulation work assigned to the cooperating agencies in the respective sectors in order to ensure the overall consistency of the HPMP
- Assist the country in designing a comprehensive monitoring system controlling the functioning of the licensing system.
- Organize stakeholder consultation meetings and ensure the participation of all stakeholders

- Prepare a fund mobilization strategy on a country-by-country basis taking into account the needs and the available sources of potential co-funding and financial incentives
- Carry out required supervision missions
- Based on the inputs from the cooperating agencies and the national stakeholders prepare and discuss and agree upon with the stakeholders on the draft and the final versions of the HPMP to be submitted to the Executive Committee
- Submit the HPMP to the ExCom, lead the discussions with the Secretariat and ExCom, provide clarification, undertake modifications etc.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

55th Executive Committee of the
Multilateral Fund for the Implementation
of the Montreal Protocol

UNIDO 2008 Work Programme Amendment

55th ExCom

Country	Type	Substance	Title of Project	Requested ammount USD	A.S.C USD	Total (incl ASC) USD	A. S. C. %	P. D.	Cooperation with IAs
Institutional Strengthening									
Montenegro	INS	CFC	Institutional Strengthening	60,000	4,500	64,500	7.5	24	Single Agency
			Institutional Strengthening Total	60,000	4,500	64,500			
MDI Project preparation									
Algeria	PRP	CFC	MDI Project preparation	30,000	2,250	32,250	7.5	12	Single Agency
Venezuela	PRP	CFC	MDI Project preparation	40,000	3,000	43,000	7.5	12	Single Agency
Syria	PRP	CFC	MDI Project preparation	40,000	3,000	43,000	7.5	12	Single Agency
			MDI Project preparation Total	110,000	8,250	118,250			
MDI Transitional Strategy									
Korea, DPR	TAS	CFC	MDI Transitional Strategy	30,000	2,700	32,700	9	12	Single Agency
Mongolia	TAS	CFC	MDI Transitional Strategy	30,000	2,700	32,700	9	12	Single Agency
			MDI Transitional Strategy Total	60,000	5,400	65,400			
Methyl Bromide Technical Assistance									
Colombia	TAS	MBR	Methyl Bromide Assistance	40,000	3,600	43,600	9	12	Single Agency
			Methyl Bromide Assistance Total	40,000	3,600	43,600			

Country	Type	Substance	Title of Project	Requested ammount USD	A.S.C USD	Total (incl ASC) USD	A.S.C. %	P.D.	Cooperation with IAs
Preparation HCFC Phase out Management Plan (HPMP)									
Albania	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Algeria	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Argentina	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating ($ 691,763)
Bahrain	PRP	HCFC22/141b	Phase out Management Plan	61,000	4,575	65,575	7.5	12	UNEP lead
Bosnia and Herzegovina	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Cameroon	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
China	PRP	HCFC22/141b	Phase out Management Plan	580,250	43,519	623,769	7.5	12	UNDP lead, WB/UNEP cooperating
Croatia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Egypt	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Eritrea	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Honduras	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP cooperating
India	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating
Indonesia	PRP	HCFC22/141b	Phase out Management Plan	214,500	16,088	230,588	7.5	12	UNDP lead, WB cooperating
Iran	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Iraq	PRP	HCFC22/141b	Phase out Management Plan	299,302	22,448	321,750	7.5	12	UNEP lead
Jordan	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Kenya	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Korea, DPR	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Kuwait	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Libya	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Macedonia, FYR	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Madagascar	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
Malaysia	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Mexico	PRP	HCFC22/141b	Phase out Management Plan	321,750	24,131	345,882	7.5	12	UNDP cooperating
Moldova	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNDP lead
Montenegro	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Morocco	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Nicaragua	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Niger	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP cooperating
Nigeria	PRP	HCFC22/141b	Phase out Management Plan	196,000	14,700	210,700	7.5	12	UNDP lead
Oman	PRP	HCFC22/141b	Phase out Management Plan	190,000	14,250	204,250	7.5	12	UNEP cooperating
Pakistan	PRP	HCFC22/141b	Phase out Management Plan	321,750	24,131	345,881	7.5	12	World Bank Lead
Qatar	PRP	HCFC22/141b	Phase out Management Plan	127,500	9,563	137,063	7.5	12	UNEP cooperating
Saudi Arabia	PRP	HCFC22/141b	Phase out Management Plan	547,000	41,025	588,025	7.5	12	UNEP cooperating
Senegal	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Serbia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
South Africa	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Sudan	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Syria	PRP	HCFC22/141b	Phase out Management Plan	392,000	29,400	421,400	7.5	12	Single Agency
Tunisia	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Turkey	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Turkmenistan	PRP	HCFC22/141b	Phase out Management Plan	244,650	18,349	262,999	7.5	12	Single Agency
Venezuela	PRP	HCFC22/141b	Phase out Management Plan	643,500	48,263	691,763	7.5	12	Single Agency
Yemen	PRP	HCFC22/141b	Phase out Management Plan	122,326	9,174	131,500	7.5	12	UNEP lead
			Phase out Management Plan Total	12,225,764	916,932	13,142,696			
			Grand Total	12,495,764	938,682	13,434,446			

Algeria: Request for technical assistance to prepare CFC phase-out project in manufacture of Aerosol Metered Dose Inhalers (MDIs) and MDI transition strategy

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

Name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
Growth patterns of CFC-MDI production over the past five years;
Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
Each production facility's plan for phasing out CFC consumption; and
The number of non-CFC MDIs and DPIs sold or distributed within the Party, by active ingredient, brand/manufacturer, and source.

On behalf of the Government of Algeria, UNIDO is submitting a request for the preparation of an MDI conversion project as well for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI production and consumption sectors. Data gathered showed that Algeria does manufacture CFC MDIs and also imports them. It also showed that the trends of both CFC manufacture and non-CFC MDIs imports are increasing.

The objectives of the future project would be to phase-out the use of CFC-11 and CFC-12 in manufacture of Salbutamol, as Aerosol Metered Dose Inhalers (MDIs) at the Algerian Pharmaceutical Laboratory (LPA). The conversion of Algerian Pharmaceutical Laboratory (LPA) to the non-CFC based MDl product with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population in Algeria and thus facilitating access to vital medication for poor people in this country. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Algeria owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and environment.

The CFC National Phase-out Plan for Algeria was approved by 53rd ExCom meeting in November 2007 and resulted in the complete phase-out of CFCs between 2007 and 2010. The project addressed all the remaining consumption of CFCs, which was 302.6 ODP tonnes and marginal other ODS (Methyl Chloroform (TCA)), which was 96.5 ODP tonnes. The project included training, technical assistance and investment activities. The ODS consumption for the MDI sector (5.96 MT of CFCs in 2006) was not addressed in this project due to its small consumption quantity used in the production of only one MDI Salbutamol product. Another reason is that the CFC consumption, which is mostly in the refrigeration sector was controlled by the NOU of the Ministry for Environment and the CFC consumption in the pharmaceutical sector had to be controlled by the Ministry of Health. The NPP would allow Algeria to phase-out its CFCs consumption and ODS consumption listed under Annex B groups I & II by January 2010 and to phase out marginal Methyl Chloroform (TCA) consumptions by January 2015. The project budget is US$ 921,500.

2. Chronic respiratory diseases in Algeria

In middle-income countries, such as Algeria, COPD and asthma are emerging as public health problems. However, the prevalence of COPD is probably underestimated, since it is not usually diagnosed until it is clinically apparent and moderately advanced. COPD affects men more frequently than women, usually appears after 45 years of age, and increases in frequency with age. Tobacco smoking is the single most important factor in the genesis of COPD and is responsible for more than 75% of cases worldwide but other environmental risk factors are also known. In addition, COPD is associated with acute respiratory infections in children and low socioeconomic status. Substantial impairment of lung function is also often found in patients cured of tuberculosis, but with extensive residual fibrosis. The Asthma prevalence in Algeria is about 4.0 %.

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

The Algerian Pharmaceutical Laboratory LPA, the producer of MDIs in Algeria is 100% Algerian owned. It was founded in 1991.

The address of the company in Algeria:
LABORATOIRE PHARMACEUTIQUE ALGERIEN (LPA)
Z,I Boudouaou Est W.Boumerdes
35400 Algérie
Switchboard Phone Number: +213 24 84 32 20
Supply Direction Phone Number : +213 24 84 39 49
Fax Number : +213 24 84 24 92

The company produces only one type MDI, i.e. Salbutamol and consumed only 8.58 MT of CFCs in 2007.

SALBUTAMOL is being produced under the license from the laboratory CHIESI, Italy. LPA owns one line of aerosol production. It came into service in 2005. The production capacity of this line is 5 million units/year.

4. Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/year) and growth patterns of CFC-MDI production over the past five years

The Algerian Pharmaceutical Laboratory (LPA) consumes both CFC-11 and CFC-12 in the manufacture of aerosol MDIs. The CFC-11 is used for the preparation of an aerosol suspension of the active ingredient to facilitate filling the precise quantity into the open aerosol MDI container, after which the MDI aerosol container is closed with the aerosol metering valve, and the CFC-12 that acts as the aerosol "propellant" is injected into the aerosol container under pressure through the metering valve. This production process applies for all CFC aerosol products according to Algerian Health Ministry, specifications for the MDI product - Salbutamol.

Table 2. Manufactured CFC - MDI product

Active Ingredient	Description	Quantity	Presentation
Salbutamol	Aerosol suspension	Each inhalator contains Salbutamol 20mg or equivalent.	Inhalator flask with 200 doses of 100 mcg

4.1. Annual Consumption of CFC Propellants Used in Production

The CFC Consumption at LPA, and units produced by year is given in the table below for Year 2006 and 2007.

Table 3. Annual CFC consumption and MDI units produced in 2006 and 2007

Year	**2006**	**2007**
CFCs Consumption (Tons)		
CFC- 11	1, 650	2, 370
CFC -12	4, 310	6, 210
Total CFC annual consumption	5, 960	8, 580
Units manufactured		
Salbutamol (VENTMAX)	333 000	480 000

5. Existing equipment installed to manufacture CFC-MDI and alternatives contemplated

5.1. Existing workshop equipment for production of Ventmax

The initial installation of the line for MDI production was in 2005 and the first actual MDI production was launched in 2006.

The company is applying the established CFC-MDIs formulation and filling technology in the MDI production line. The production line was equipped from well known European suppliers:

Table 4. Process equipment

N° EQUIPMENT	EQUIPMENT	MAKE/MODEL	YEAR
01	FILLING MACHINE	COSTER 6AGV/M/PHARMA	2004
02	PREPARATION TANK 100L	PELLEGRINI	2004
03	PRODUCT RECIRCULATION PUMP	CSF	2004
04	TANK FOR EXCIPIENTS PRE-DISPERSION AND CONCENTRATE SUSPENSION PREPARATION WITH HOMOGENIZER SILVERSON	GRAMI	2004
05	INSTALLATION ON LOADING CELL	PELLEGRINI	2004
06	FILTER (PROTECTION OF THE PUMP)	/	2004
07	PUMP 25-PZG FOR F12	COSTER	2004
08	ACCUMULATOR WITH MEMBRANE	COSTER	2004
09	PUMP 25-PZG FOR F11	COSTER	2004
10	FREON 11 TANKS	/	2004
11	ACCUMULATEUR WITH MEMBRANE	COSTER	2004
12	FREON 12 TANKS	/	2004
13	PUMP FOR FREON 12 TRANSFER	COSTER	2004
14	HEAT EXCHANGERS FOR FREON 11 AND 12	/	2004
15	WORKING STATION WITH LAMINAIR AIR FLOW HOOD	STERIL	2005

Table 5. Packaging equipment

N° EQUIPMENT	EQUIPMENT	MAKE/MODEL	YEAR
16	CONVEYOR BELT	COSTER	2004
17	LOADING TABLE N°1	COSTER	2004
18	CHECKWEITHER NR1 AS	RAMSEY	2004
19	LABELING MACHINE	ETIPACK	2004
20	TRAY LOADING	COSTER	2004
21	LOADING TABLE N°2	COSTER	2004
22	CHECKWEITHER NR2 AS	RAMSEY	2004
23	CHEKED CAN IN CARTON BOX	COSTER	2004
24	WORKING TABLE FOR MANUEL SPRAY TEST OF VALVES	MERCURY	2005
25	CARTONING MACHINE AV	CAM	2004
26	LABELING MACHINE N°2	ETIPACK	2004

6. Plan for phasing out CFC consumption in the production facility

6.1. Replacement technology and equipment

The most acceptable replacement technology is the use of HFA instead of CFC as a propellant in the MDI production. This technology is now widely used in most pharmaceutical companies worldwide and all new drugs formulations are based on this propellant.

Therefore, LPA will need the HFA technology with regard to MDI formulation and new filling machines to be installed at its premises. A corresponding training the working staff on the new machinery is also needed. The existing machinery cannot be retrofit to manufacture HFC MDIs, but still there are some components of the line could be used.

6.2. Equipment required for the HFA MDI production

A whole production line will include:
1 - HFA circulating pump
2 - HFA pump
3 - Single aerosol assisted manual filling installation

6.3. Equipment in place and not needed to be replaced

1 - Labelling machine
2 - Checkweigher

6.4. Plan for phasing out CFC consumption in the production facility

New productions techniques and processes for the conversion of most of LPA CFC MDIs into HFC MDIs LPA will need completely different production equipment.

The HFC 134a will replace both CFC-11 and CFC-12 in the CFC MDI formulation.
Due to the gas nature of the HFC-134a at the normal atmospheric pressure the suspension (HFC-134a /active ingredients) preparation would have to be made in a pressurized preparation mixer, then the prepared slurry suspension would be dosed through the filling machine into the aerosol can.

The key transition program steps for technology transfer for LPA are:

• Agree specifications for an assisted manually operated pressure filling line, which has a capacity: with dosing valve 5 -10 cans/minute (depending as on the volume and valve to be filled).

• Procure, install commission and validate the production line.
• Agree performance based product specifications for the developed product. The objective is to replace the current CFC Salbutamol marketed product with an HFA equivalent product that will meet the current regulatory requirements of the Algerian Health Authority.
• Selection of all materials and primary packaging components (valve, canister and actuator), not the secondary packaging components (carton, package insert etc.). The selection process and evaluation must take in to consideration local and/ or current suppliers that may offer a more cost competitive product.
• Package and formulation development supported by short term, performance data. Data package to be reviewed with client for acceptability prior to undertaking stability phase.
• Subject to agreement generation of a minimum of 6 months 40C 75RH unprotected stability/performance data on the selected package/ formulation. The full stability test data package to be reviewed with LPA for acceptability.
• Generation of all required documentation and reports, technology transfer of all analytical and manufacturing methods.
• Verification of successful technology transfer of each product to LPA manufacturing facility. Including verification of analytical method transfer, assistance and training on-site of analytical and manufacturing personnel.
• Manufacture of Registration/ Stability batches of the product(s).
• Supply data suitable for submission to Algerian Health Authorities for marketing approval.
• De-commissioning of all CFC dedicated manufacturing equipment and exhaustion of residual CFC stocks.

7. Number of non-CFC and CFC-free MDIs and DPI sold or distributed by active ingredient, brand/manufacturer, and source

The table below presents the quantities of various types of CFC MDIs, HFA MDIs and DPIs imported into the country in 2004 - 2007.

The total amount of all imported inhalators in Algeria in 2007 was about 3.8 million units including CFC and HFA MDIs and DPIs, although the quantities of CFC-free MDIs exceeded the quantities of CFC MDIs. This tendency was conditioned by the implementation of the Montreal Protocol Agreement. At the time of the project formulation UNIDO would approach the Drug Administration for detailed discussions on the Transitional Strategy formulation and implementation and precise analyses of the MDI quantities imported into the country in the past years. The Ministry confirmed that the two types of MDIs, i.e. CFC and CFC-free MDIs are available on the local market. Small quantities of DPIs are also available on the market, although too expensive for the majority of Algerian population.

The LPA des not export MDIs to other countries in the region.

Table 7. Imports of MDIs/DPIs into Algeria in 2004-2007

7.1. Imports of MDIs/DPIs into Algeria in 2004

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	209,704	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	28,000	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/BOUFF	FL/80DOSES	8,852	UK
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	99,249	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	19,500	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	100,000	ITALY
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	4,000	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	1,000	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	UK
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	5,000	FRANCE
IPRATROPIUM BROMURE	Propellant: monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	9,000	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	20,000	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	139,832	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,410,958	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	816,499	UK
SALBUTAMOL	HFA 1341a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,651	Italy
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	242,107	UK

SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	300,000	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,200	Italy
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,500	FRANCE
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	14,499	UK
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	250/50µG	FL/60DOSES	59,991	UK
SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	20,000	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	UK
BUDESONIDE	HFA 134a	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	34,880	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	30,641	FRANCE
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	149,993	FRANCE

7.2. Imports of MDIs/DPIs into Algeria in 2005

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Producer	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF.	FL/200DOSES	324,560	GSK	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	41,000	CIPLA	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	7,500	GSK	UK
BECLOMETHASONE	Norflurane (HFA)	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	220,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	18,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	1,000	CHIESI	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	GSK	UK
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	5,500	GSK	FRANCE
IPRATROPIUM BROMIDE	Propellant : monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	12,000	BOEHRINGER	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	22,340	CIPLA	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,100	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	1,600,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	28,000	CHIESI	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	250,000	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	220,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,600	CHIESI	FRANCE
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,300	GSK	FRANCE

SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	16,546	GSK	UK
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	250/50µG	FL/60DOSES	59,991	GSK	UK
SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	22,000	GSK	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	GSK	UK
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	36,000	CIPLA	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	34,000	ASTRA ZENECA	FRANCE
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	160,000	SERVIER	FRANCE

7.3. Imports of MDIs/DPIs into Algeria in 2006

Name of drug	Propellant	Generic name	Form	Dose/unit	Strength	Quantity	Producer	Country
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a)	VENTOLINE	AÉRO	100µG/PUFF.	FL/200DOSES	246,000	GSK	FRANCE
BECLOMETHASONE	CFCs	BECLATE	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	34,0000	CIPLA	INDIA
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	8,852	GSK	UK
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	30,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	2,500	CHIESI	FRANCE

BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	12,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	124,000	CHIESI	ITALY
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	10,000	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	2,100	CHIESI	ITALY
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a).	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	34,955	GSK	UK
BECLOMETHASONE	Norflurane (HFA)	BECLOJET	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	15,100	CHIESI	FRANCE
BECLOMETHASONE	Norflurane (tetrafluoroethane or HFA 134a)	BECOTIDE	AÉRO BUCC.	250µG/PUFF	FL/80DOSES	10,500	GSK	FRANCE
BECLOMETHASONE	Norflurane	CLENIL	AÉRO BUCC.	250µG/PUFF	FL/200DOSES	76,432	CHIESI	FRANCE
IPRATROPIUM BROMURE	Propellant : monofluorotrichloromethane	ATROVENT	AÉRO	20µG/DOSE	FL/200BOUFF.	10,000	BOEHRINGER	FRANCE
SALBUTAMOL	CFCs	ASTHALIN	AÉRO	100µG/PUFF	FL/200DOSES	234,657	CIPLA	INDIA
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	2,650,00	GSK	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	589,000	GSK	UK
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	25,000	CHIESI	FRANCE
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO.	100µG/PUFF	FL/200DOSES	244,453	GSK	UK
SALBUTAMOL	Norflurane (tetrafluoroethane or HFA 134a).	VENTOLINE	AÉRO	100µG/PUFF	FL/200DOSES	180,000	GSK	FRANCE
SALBUTAMOL	HFA 134a	VENTMAX	AÉRO	100µG/PUFF	FL/200DOSES	20,200	CHIESI	FRANCE
SALBUTAMOL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG/PUFF	FL/120DOSES	1,500	GSK	FRANCE
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	100/50µG	FL/60DOSES	87,567	GSK	UK

SALMETEROL	Norflurane (or tetrafluoroethane or HFA-134a).	SEREVENT	AÉRO	25µG	FL/120DOSES	23,000	GSK	SPAIN
SALMETEROL (XINAFOATE)/FLUTICASONE (PROPIONATE)	Powder for inhalation in single dose sachet container	SERETIDE DISKUS	AÉRO	500/50µG	FL/60DOSES	7,192	GSK	UK
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	20,000	CIPLA	INDIA
BUDESONIDE	Trichlorofluoromethane (CFC 11), dichlorotétrafluoroéthane (cryofluorane or CFC 114), dichlorodifluorométhane (CFC 12).	PULMICORT	AÉRO	200µG/PUFF	FL/100DOSES	28,000	ASTRA ZENECA	FRANCE
BUDESONIDE	CFCs	BUDECORT	AÉRO	200µ/PUFF	FL/200DOSES	16,000	CIPLA	INDIA
FUSAFUNGINE	NORFLURANE	LOCABIOTAL	AÉRO	1%	FL/5ML	78,657	SERVIER	FRANCE

7.4. Imports of MDIs/DPIs into Algeria in 2007

Producer	Country	Brand name	Generic name	Type	Quantity 2007	Dosage	Strength	CFC/HFA MDIs and DPIs
CHEISI S.A.	ITALY	CLENIL 250	BECLOMETHASONE	Aerosol	239.045	250µG/puff	FL/200 doses	Norflurane
ASTRA	FRANCE	BRICANYL	Terbutaline	Aerosol	21.678	250 µG /puff	FL/200 doses	(Freon 11), cryoflurane (Freon 114), (Fréon 12)
ASTRA	FRANCE	PULMICORT	BECLOMETHASONE	Aerosol	40.931	200µG/puff	FL/200 doses	(CFC 11), (cryofluorane or CFC 114), (CFC 12)
GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	50µG /dose	FL/120 doses	Norflurane (tetrafluoroethane or HFA-134a).

GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	125µG /dose	FL/120 doses	Norflurane (tetrafluoroethane or HFA-134a).
GLAXO SMITHKLINE	FRANCE	FLIXOTIDE	Fluticasone	Oral Inhaler Suspension	-	250µG /dose	FL/60 doses	Norflurane (tetrafluoroethane or HFA-134a).
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)Fluticasone (propionate)	Inhaler Powder	91.474	500 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)/Fluticasone (propionate)	Inhaler Powder	219.963	250 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
GLAXO SMITHKLINE	United Kingdom	SERETIDE DISKUS	Salmeterol (xinafoate)/Fluticasone (propionate)	Inhaler Powder	38.681	100 /50µg	FL/60 doses	Powder for inhalation in single dose sachet container
BOEHRINGER INGELHEIM	GERMANY	ATROVENT	IPRATROPIUM BROMURE	Pressurised Flask Inhaler Suspension	94.764	20µG Dose	FL/200 doses	Propellant : monofluorotrichloromethane
NOVARTIS PHARAM S.A.	FRANCE	FORADIL	Formotérol	Powder for Inhaler	162.3	12 micro G	B/30 ET B/60	Powder for inhalation in capsules
CHEISI S.A.	ITALY	BECLOJET	BECLOMETASONE	Oral Inhaler Suspension	22.499	250 µG / Breath	FL/200 doses+ Integrated inhalation chamber	Norflurane (HFA)
PFIZER	FRANCE	COLLU-HEXTRIL	HEXETIDINE	Oral Medication	587.646	0.20%	FL/40ML	Nitrogen
BOUCHARA-RECORDATI	FRANCE	HEXASPRAY	Biclotymol	Oral Medication	166.276	0,75MG / 30G	Pressurised Flask/30G	Nitrogen

FUMOUZE	FRANCE	STERIMAR	Microdiffusion physiologique d'eau de mer	Oral Medication	-	Sea water: 31,82ml, Purified water qsp 100ml,	F/100 ml	Nitrogen
Laboratoires GILBERT	FRANCE	MARIMER	Eau de mer isotonique microdiffusée	Sterilized Sea Water physiologic al Solution	-	Sea water: 31,82mlPurifi ed water qsp 100ml,	Pulverising Flask of 100 ml	Nitrogen
Laboratoires PIERRE FABRE MÉDICAMENT Laboratoire Pierre Fabre Oral Care	FRANCE	ELUDRIL	Chlorhexidine, Tétracaïne	Oral Medication	-	50 mg/15 mg/100ml	FL/55ml	Nitrogen

8. The Transition Strategy for the elimination MDIs with CFCs and the introduction of the replacement CFC MDIs in Algeria

The national transition strategy (to be prepaed under the NPP) as a part of the MDI conversion project will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of the Ministry of Health, physicians, health professionals, pharmaceutical companies/association and the community.

The education and sensitising campaign for the introduction of new products (HFA MDIs) will therefore be both necessary and challenging in this situation. Considering the above-mentioned elements the implementation of an education programme involving health professionals, patients, their families and the community from the very beginning becomes a priority, led by the Ministry of Health and Medical Education.

9. Project duration period

Until the new production line is installed and is ready for production of HFA MDIs on the commercial basis, LPA would continue the production of CFC MDIs. The first step would be to start with the conversion of one product, which would likely be " VENTMAX " Salbutamol. The conversion period would take about two years until LPA finishes all the tests and obtaining a license and marketing authorization from the Ministry of Health of Algeria provided that a technology provider selected by UNIDO would complete the task of new products formulation and 6 months testing at its premises.

10. Urgent conversion to HFA production is needed

For Algeria and particularly for the health sector and environment the project is of a very high importance, because the Government of Algeria need to urgently convert this company to non-CFC MDI production in order to provide locally produced cheaper MDIs for thousands of asthma and COPD patients in Algeria, specially those that have low income.

Another urgency to have HFA MDIs available in the country is the absence of imported inhalers in Algeria and if they could be even available in the black market they are not affordable for most of Algerian population due to their higher price in comparison with those produced by the LPA. The low income of the majority of the people in Algeria and the absence of good health insurance programs in most of the countries of the region characterize the pricing policy of the LPA with regard to the MDIs.

Revised
PTC/MEA/VS
UNIDO
June 2008

DPR Korea: Technical assistance to prepare MDI transition strategy (US $30,000)

1. Background

DPR Korea has a planned economy, supervised by the National Planning Commission.

The Ministry of Public Health is responsible for the supervision of the State health services. There is no private sector.

The number of asthma patients in DPRK is stable. Around 4 % of the population suffer from Asthma and COPD, i.e. 900,000 people out of about 23,000,000 total population.

In order to be prepared for any problems associated with the replacement of CFC MDIs with alternatives such as HFA MDIs and powder inhalers, the Ministry of Public Health expressed their interest in having a transition strategy formulated by UNIDO.

2. Project description

The Government of DPR Korea has requested UNIDO to formulate the Transitional Strategy for the MDI Sector. The Government confirmed their interest in having such a strategy formulated by UNIDO and also provided data on the MDI imports in DPRK for the past three years.

On behalf of the Government of DPR Korea, UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector.

Data gathered by UNIDO show that DPR Korea does not manufacture CFC MDIs. The available data indicates that 2,311,600 units were imported in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007. These imports are from Altayvitamin Company in the Russian Federation. The generic names are Salbutamol and Beclamethasone.

The incidences of chronic destructive pulmonary disease (COPD) and asthma in DPR Korea are stable. A steady supply of MDIs is needed to meet patients' needs.

3. National MDI Strategy

The national strategy on replacement of CFC-based MDIs with alternatives is envisaged as follows:

- Continued analysis of MDI market consumption, sources of supply and estimates of future trends.
- Evaluation of alternative products and their economic impact on the State health services.
- Supervise the transition to alternatives.
- Regulations will be introduced to support the phase-out of CFC-based MDIs and to ensure the monitoring of imports of MDIs, conforming to the provisions of the Montreal Protocol and its amendments..
- A programme to raise physician awareness and patient acceptance of alternatives to CFC-MDIs.
- The requested funding of US$ 30,000 for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs.

4. Funding

The requested funding of US$ 30,000 for the development of an MDI transition strategy will allow the establishment of a clear schedule for import of alternatives to CFC-MDIs.

5. Survey of MDIs in DPR Korea

In support of their submission and based on decision 51/34, UNIDO has worked together with the Ministry of Public Health to survey the situation with regards to the supply of MDIs and their non-CFC equivalents in DPR Korea. The situation is reflected in Exhibit 1 attached on page 3 and is as follows:

- CFC MDIs are available but there are no non-CFC equivalents, neither HCFC products nor powder inhalers.
- Imports of CFC MDIs decreased slightly from 2005-2007. 2,311,600 units were imported in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007.
- Prices for the last three years have remained stable.

A comprehensive table listing CFC MDIs imported, sold or distributed within the country, identified by active ingredient, manufacturer and source, is summarised in Exhibit 1 below:

6. Summary

DPR Korea does not manufacture CFC MDIs.

Imports of CFC MDIs were 2,311,600 units in 2005, 2,213,440 in 2006 and 1,964,050 units in 2007. The source was Russia and the price was a uniform US$ 2 per unit. Generic names are Salbutamol and Beclamethasone.

The number of asthma patients in DPRK is stable. Around 4 % of the population suffer from Asthma and COPD, i.e. 900,000 people.

The project preparation request for US$ 30,000 is being submitted to enable the smooth transition to non-CFC MDIs in DPR Korea, therefore phasing out CFC consumption in the MDI sector.

PTC/MBR/VS
UNIDO
May 2008

Exhibit 1: Market share of MDIs

MDI brand name	Active ingredient	Manufacturer	Importer	Cost of one MDI, US$	Propellant	MDI units imported/year		
						2005	2006	2007
Ventalex	Salbutamol	Altaivitaminy, Russia	Mannyon Public Health Company	2	CFC	2,126,000	2,013,400	1,867,400
Beclex	Beclamethasone	Altaivitaminy, Russia	Mannyon Public Health Company	2	CFC	185,600	200,040	196,650
MDI brand name	**Date approved by local drug administration**	**Date authorised for marketing**		**Date launched on the territory of the country**				
Ventalex	Department of Drug Affairs, Ministry of Public Health	November 2004, 2005, 2006		February 2005, 2006, 2007				
Beclex	Department of Drug Affairs, Ministry of Public Health	November 2004, 2005, 2006		February 2005, 2006, 2007				

Source: Ministry of Public Health of DPRK

Project Concept

Country:	Mongolia
Title:	Technical Assistance to Prepare an MDI Transitional Strategy
Background:	UNIDO received an official Government request to prepare an MDI transitional Strategy in Mongolia
Project Duration:	12 months
Project Budget:	32,700 (including 7.5% Agency Support Costs)
Implementing Agency:	UNIDO
Coordinating Agency:	Ministry of Environment

Project Summary

1. Background

Mongolia is a country in transition from a planned economy to being market oriented.

The health services fall under the Ministry of Health.

The Government of Mongolia has requested UNIDO to formulate the Transitional Strategy for the MDI Sector. The Government confirmed their interest in having such a strategy formulated by UNIDO and also provided data on the MDI imports in Mongolia for the three years 2003-2005.

Mongolia imports MDIs from the Russian Federation. The generic name is Salbutamol.

The number of asthma patients in Mongolia is stable. Around 1.2 % of the population of 2,500,000 is reported to suffer from Asthma and COPD, i.e. about 30,000 people. This unusually low incidence in global terms may result from under-reporting and reluctance by the rural population to seek medical treatment from non-traditional sources.

In order to be prepared for any problems associated with the replacement of CFC MDIs with HFA MDIs, the Ministry of Health expressed their interest in having a transition strategy to be

formulated by UNIDO.

2. Project description

On behalf of the Government of Mongolia, UNIDO is submitting a request for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI consumption sector.

Data gathered by UNIDO show that Mongolia does not manufacture CFC MDIs.

There is an overall concern on the part of the Government of Mongolia and its health authorities about the MDI sub-sector. The incidences of chronic destructive pulmonary disease (COPD) and asthma are stable and there is a need to ensure a steady supply of MDIs to meet these patients' needs.

3. National Strategy

The national strategy on replacement of CFC-based MDIs with alternatives is envisaged as follows:

(a) Better study and analysis of current MDI market consumption, supply sources and future trends.

(b) Analysis of alternative products and their effects and health benefits.

(c) Co-operation with the main importers and the public health authorities to define affordable alternative medications.

(d) Development of multi-year national planning on imports to ensure a smooth transition to alternatives.

(e) Regulations will be put in place to support the phase-out of these ozone depleting products and to ensure the monitoring of imports of MDIs conforming to the provisions of the Montreal Protocol and its amendments.

(f) A programme to raise physician awareness and patient acceptance of alternatives to CFC-MDIs. This will involve training and targeted awareness activities, to increase confidence and ensure acceptance of the alternative products by both patients and doctors.

Health authorities are in general not aware of the requirements of the Montreal Protocol to phase out CFCs in MDIs.

4. Funding

The requested funding of US$ 30,000 for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs.

5. Survey of MDIs in Mongolia

In support of their submission and based on decision 51/34, UNIDO has worked together with the Regulatory Agency of the Government, State Specialized Inspection Agency, Health Monitoring Bureau. The situation has been surveyed with regards to the supply of MDIs and their non-CFC equivalents in Mongolia and can be briefly described as follows:

(a) There is no manufacture of CFC or HCFC MDIs in Mongolia.

(b) Only imported CFC MDIs are available. There are no HCFC products and no powder inhalers.

(b) Imports of CFC MDIs were 10,000 units in 2003, 8,538 in 2004 and 6,480 units in 2005. The source was Russia and the price was US$ 2 per unit.

The country has a stable pricing for unit costs, as prices for the last three years for specific products have remained the same although the supplier has changed.

The reason for the sharp decline from 2003 to 2004 and then to 2005 is believed to have been over-stocking in 2003.

A comprehensive table listing CFC MDIs imported, sold or distributed within the country, identified by active ingredient, manufacturer and source, is summarised in Exhibit 1 below:

Exhibit 1 **MDIs in Mongolia**

Active ingredient	**Manufacturer**	**Propellant**	**MDI units imported/year**		
			2003	**2004**	**2005**
Salbutamol, aerosal-12ml	Moschimfarm, Russia	CFC		8,538	6,480
Salbutamol, aerosal-12ml	Altaivitamin, Russia	CFC	10,000		

Source - Regulatory Agency of the Government, State Specialized Inspection Agency, Health Monitoring Bureau

6. Summary

The project preparation request for US$ 30,000 is being submitted to enable the smooth transition to non-CFC MDIs in Mongolia, therefore phasing out CFC consumption in the MDI sector.

Imports of CFC MDIs were 10,000 units in 2003, 8,538 in 2004 and 6,480 units in 2005. The source was Russia and the price was US$ 2 per unit. Generic name is Salbutamol. Product had been over-stocked in 2003.

The number of asthma patients in Mongolia is stable. Around 1.2 % of the population of 2,500,000 is reported to suffer from Asthma and COPD, i.e. about 30,000 people. This unusually low incidence in global terms may result from under-reporting and reluctance by the rural population to seek medical treatment from non-traditional sources.

Project Concept

Country:	Syria
Title:	Preparation of MDI Project
Background:	UNIDO received an official Government request for the preparation of MDI project in Syria
Objectives:	To prepare a project to phase out CFC use in the production of MDIs in Syria.
Project Duration:	12 months
Project Budget:	43,000 (including 7.5% Agency Support Costs)
Implementing Agency:	UNIDO
Coordinating Agency:	Ministry of Environment

Project Summary

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

- Name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
- Type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
- Growth patterns of CFC-MDI production over the past five years;
- Whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
- Each production facility’s plan for phasing out CFC consumption; and

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

On behalf of the Government of Syria, UNIDO is submitting a request for the preparation of an MDI conversion project as well for the preparation of an MDI-transition strategy to phase-out CFC use in the MDI production and consumption sectors. Data gathered showed that Syria does manufacture CFC MDIs and also imports DPIs. It also showed that the trends of both CFC manufacture and DPIs imports are increasing.

The objectives of the investment project would be to phase-out the use of CFC-11 and CFC-12 in manufacture of Salbutamol, Beclomethasone Dipropionate, Beclomethasone Dipropionate plus Salbutamol, Fluticasone Propionate, Salmeterol and Salmeterol plus Fluticasone Propionate as Aerosol Metered Dose Inhalers (MDIs) at Kaspar-Chabani Pharma, which represent almost 100% of the consumption in the social security in Syria.

The conversion of Kaspar-Chabani Pharma to non-CFC based MDl products with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population and thus facilitating access to vital medication for millions of people. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Syria owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and environment.
Syria has no CFC production. All CFCs consumed for manufacturing and servicing purposes are imported mainly from developed countries and supplied through distributors, indenting agents and systems houses. The CFC National Phase-out Plan for Syria was approved by 49th ExCom meeting in 2006 and resulted in the complete phase-out of CFCs between 2006 and 2010. The cost of the project as approved was US$ 946,000 and it addressed all the remaining consumption of CFCs, which was 898.56 ODP tones (as of 2005). The project included training, technical assistance and investment activities. The ODS consumption in the MDI sector (25.71 MT of CFCs in 2005) was not addressed in this project. The NOU was not informed about the CFC consumption in the MDI production at K.C. Pharma, which is under control of the Ministry of Health. It is also believed that the major CFC consumption was in the refrigerator sector. Moreover, the CFC consumption in the aerosol and foam sectors was phased out in 2005. Acording to the NPP document the CFC consumption in the country was mainly in refrigeration manufacturing sector, though the consumption was reduced through implementation of the previously approved refrigeration management plan. With a series of activities proposed in the NPP, the service usage of CFCs will be

gradually reduced. With this arrangement, Syria achieved the 85% reduction target in 2007 and would achieve zero consumption by 2009 in terms of the CFC consumption. The total phase of CFCs in the MDI sector would take place in 2010.

KC Pharma’s CFC imports in 2007 were around 52 MT from a French company to cover the expected increase in demand in 2007-2008, and new orders have also been made. All of KC Pharma's CFC import requests were forwarded to the Ministry of Health in Syria due to the CFC specific role in inhalers production and in order to make customs clearance easer, since a pharmaceutical ingredient was considered by the Ministry of Health but not by the Ministry of Environment. Therefore, the NOU was not aware of the CFC consumption in the MDI sector.

2. Asthma and COPD in Syria

2.1. Population and economy

Population (2005): 18.6 million
Growth rate (2005): 2.45%
Literacy-92.5% - 87.9% - male and 73.9% - female
Health (2004): Infant mortality rate-17.1/1,000
Life expectancy- 68.47 years – male and 71.02 years - female
Workforce (6.1 million, 2004 est.): involved in providing services (including the government), in agriculture and industry and commerce.
GDP (2005nominal): $27.3 billion.
Real growth rate: 2.9%.
Per capita GDP: US$ 1,464.
Natural resources: Crude oil and natural gas, phosphates, asphalt, rock salt, marble, gypsum, iron ore, chrome, and manganese ores.
Agriculture: Products; cotton, wheat, barley, sugar beets, fruits and vegetables. **Industry:** Types-mining, manufacturing (textiles, food processing), construction, petroleum.
Trade:
Exports-US$10.2 billion: petroleum, textiles, phosphates, antiquities, fruits and vegetables, cotton. Major markets: EU, Arab countries, United States, Eastern and Central Europe.
Imports: US$10.8 billion: foodstuffs, metal and metal products, machinery, textiles, petroleum. Major suppliers-Russia, Turkey, Ukraine, China, U.S. and Japan.

2.2. Respiratory diseases in Syria

The main cause of COPD in Syria is smoking. But exposure to dusts in the workplace can also cause COPD, even if people don't smoke. SCTS’s (the Syrian Center for Tobacco Studies) population-based assessment of tobacco use in Syria showed that daily cigarette

smoking is the predominant form of smoking, affecting 51.4% of men and 11.5% of women, and that waterpipe smoking is gaining ground, affecting 20.2% of men and 4.8% of women. Waterpipe smoking is characterized by intermittent use and predominance among the young and affluent. A meeting with the Central Bureau for Statistics to check the percentage of the population using MDI products.

The prevalence of asthma in Syria is around 5-8% of the population and it is increasing at an average rate of around 5% per year. The respiratory disease child death rate in Syria is 42.55/100,000 inhabitants.

According to the Central Bureau for Statistics the 2005 statistics showed that 5.4% of Syrian population was using MDIs for asthma treatment or prevention, and the Bureau assumed that this percentage would be presently about 6%.

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

Kaspar-Chabani Pharma also known as (K.C. Pharma) was first established in 1988 as a 100% Syrian owned company.

The plants and main offices of the company are located in Aleppo, which is 360 km north off Damascus, the capital of Syria.

The main production lines in the company are for products like: Syrups, Suspensions, Ear drops, Capsules, Tablets, Film Coated Tablets, Ovules, suppositories and CFC-MDIs.

The company is the sole producer of MDIs in Syria.
Currently the company occupies a land area of 13,000 square meters, with one factory
building area of 4000 square meters.

Company address

The company name is Kaspar and Chabani Pharma (K.C.Pharma).
Address: Haian Industry Zone , Aleppo – Syria.
Telephone Number: +963 21 2656062.
Fax Number: +963 21 2656562.
E-Mail Address: info@kc-pharma.com
Website: www.kc-pharma.com
Scientific Office: Aleppo – Syria.
Tel: +963 21 4444060 - +963 21 4444068.
Mailing Address: Kaspar-Chabani Pharma
P.O.Box: 3980, Aleppo - Syria
Telephone and fax number of contact person:

The general manager Mr. Joseph Kaspar
Tel: +963 21 2656062, +963 21 4444060, +963 21 4444068.
Fax: +963 21 2656562.

3.1. MDI production facilities

The initial installation of the line for MDI production was in 1998 and the first actual MDI production was launched in 1999. The company was using the established CFC-MDIs formulation and filling techniques. The production line was equipped from well known European suppliers, i.e.:

- Suspension preparation vessel 150 littres: Pietro Pelligrini (Italy)
- Filling Machine + CFC-11 pump + recirculating system + CFC-12 pump: Coster (Italy)
- Checkweigher : Thermo Ramsey Tecnoeuropa (Italy)
- Labeling machine: Neri (Italy)

3.2. MDI line production capacity and MDI products

The current CFC-MDI production equipment capacity is 3600 cans/hour, and about 8.5 million cans/year on a single production line, single shift per day. However, the actual MDI demand met by KC Pharma in Syria in 2007 was around 2.0 million MDIs per year.

Dates of approval and production of each product

Active ingredient	Date of establishment
Salbutamol	1999
Beclomethasone Dipropionate	1999
Beclomethasone Dipropionate + Salbutamol	1999
Fluticasone Propionate	2002
Salmeterol	2003
Salmeterol + Fluticasone Propionate	2004

4. Type of CFC MDI products manufactured, active ingredients used, annual production output (units/year) and growth patterns of CFC-MDI production over the past eight years

4.1. CFC-based MDI manufacturing process at KC Pharma

KC Pharma use both CFC-11 and CFC-12 in the production of aerosol MDIs.
CFC-11 is used for the preparation of suspension with active ingredients to smooth the progress of filling the exact amount of suspension into the open aerosol MDI container, and then the metering valve is placed onto the open container and crimped with the aerosol container. CFC-12, which is a propellant is injected into the container under pressure through the metering valve.

KC Pharma products specifications

Product Name	Composition	Presentation
Butovent Spray	Salbutamol BP 100 mcg/puff	200 doses
Clenil Forte Spray	Beclomethasone Dipropionate 250 mcg/puff	200 doses
Clenil Spray	Beclomethasone Dipropionate 50 mcg/puff	200 doses
Clenil Forte jet	Beclomethasone Dipropionate 250 mcg/puff	200 doses
Clenil Compositum Spray	Beclomethasone Dipropionate 50 mcg/puff Salbutamol BP 100 mcg/puff	200 doses
Asthmatide 50	Salmeterol 25 mcg/puff Fluticasone Propionate 50 mcg/puff	120 doses
Asthmatide 125	Salmeterol 25 mcg/puff Fluticasone Propionate 125 mcg/puff	120 doses
Asthmatide 250	Salmeterol 25 mcg/puff Fluticasone Propionate 250 mcg/puff	120 doses
Flusone 44	Fluticasone Propionate 50 mcg/puff	120 doses
Flusone 110	Fluticasone Propionate 125 mcg/puff	120 doses
Flusone 220	Fluticasone Propionate 250 mcg/puff	120 doses
Asthmerol	Salmeterol 25 mcg/puff	120 doses

As mentioned in paragraph 2.1 the initial installation of the aerosol MDI line was in 1998, but its first output was in 1999.

At the very beginning the growth was between 5-10% because the MDI products were new ones in the market but in years 2002-2004 the growth became around 10-15 % and it increased up to 15-20% in 2005-2006. The figures of 2007 show an unprecedented growth of 40

% due to many reasons; amongst them was the growing number of population and increasing numbers of the Iraqi refugees and the expansion of markets abroad.

Annual production figures 1999-2002 (in number of units) at K.C. Pharma

MDI products	**1999**	**2000**	**2001**	**2002**
Butovent Spray	487900	513000	543000	582000
Clenil Forte Spray	46900	49000	52200	55850
Clenil Spray	63700	66900	71000	75800
Clenil Forte jet	2900	3000	3200	3400
Clenil Compositum Spray	45500	47800	51000	54200
Total	646900	679700	720400	771250

Annual CFC consumption (1999-2002)

Year	1999	2000	2001	2002	2003
	Annual consumption by (MT)				
CFC-11	4.36	4.58	4.86	5.20	5.89
CFC-12	10.18	10.70	11.34	12.14	13.76
Total	14.55	15.29	16.20	17.35	19.66

Annual production figures 2003-2007

Product	2003	2004	2005	2006	2007
Butovent Spray	634000	697000	780400	874000	1235000
Clenil Forte Spray	61000	67000	75000	84000	99300
Clenil Spray	83000	90900	101800	114000	141000
Clenil Forte jet	3700	4100	4600	5100	-
Clenil Compositum Spray	59050	65000	72800	81500	104700
Asthmatide 50		4100	8200	6400	12400
Asthmatide 125		11600	25400	32600	49900
Asthmatide 250		7400	16900	23800	36200
Flusone 44	6100	4700	5500	7100	9500
Flusone 110	7500	11700	7600	14200	16800
Flusone 220	4900	7500	6800	10800	12700
Asthmerol	14600	32500	37800	39100	46200
Total	873850	1003500	1142800	1292600	1763700

Annual CFC consumption (1999-2007)

Year	2004	2005	2006	2007
	Annual consumption by (MT)			
CFC -11	6.77	7.71	8.72	11.90
CFC-12	15.79	17.99	20.35	27.76
Total	22.57	25.71	29.08	39.68

4.2. Existing equipment installed at KC Pharma to manufacture CFC-MDI

The list of existing line machinery and equipment for production of CFC products:

- Suspension preparation vessel (150 littres) is from Pietro Pelligrini (Italy)
- Filling Machine + CFC-11 pump + recirculating system + CFC-12 pump are from Coster (Italy)
- Checkweigher is from Thermo Ramsey Tecnoeuropa (Italy)
- Labeling machine is from Neri (Italy)

All these machines were purchased in 1998 when the company decided to start manufacturing CFC MDIs in Syria. It should be noted that the filling machine cannot be retrofitted to be compatible with a HFA MDI line.

4.3. Required HFA machines for the conversion plan

4.3.1. Replacement technology and equipment

The most acceptable replacement technology is the use of HFA instead of CFC as a propellant in the MDI production. This technology is now widely used in most pharmaceutical companies worldwide and all new drugs formulations are based on this propellant.

Therefore, KC Pharma will need the HFA technology with regard to MDI formulation and new filling machines to be installed at its premises. A corresponding training the working staff on the new machinery is also needed. The existing machinery cannot be retrofit to manufacture HFC MDIs, but still there are some components of the line could be used.

4.3.2. Equipment required for the HFA-based MDI production

A whole production line will include:
1 - Mixing Vacuum preparation vessel 150l for single-stage filling production
2 - HFA circulating pump
3 - HFA pump
4 - Aerosol filling machine Macromat P 2045

4.3.3. Equipment in place and not needed to be replaced

1-labelling machine
2-checkweigher

4.4. Plan for phasing out CFC consumption in the production facility

New productions techniques and processes for the conversion of most of KC Pharma CFC MDIs into HFC MDIs KC Pharma will need completely different production equipment.

The HFC-134a will replace both CFC-11 and CFC-12 in the CFC MDI formulation.
Due to the gas nature of the HFC-134a at the normal atmospheric pressure the suspension (HFC-134a /active ingredients) preparation would have to be made in a pressurized preparation mixer, then the prepared slurry suspension would be dosed through the filling machine into the aerosol can.

5. Project duration period

Until the new production line is installed and is ready for production of HFA MDIs on the commercial basis, KC Pharma would continue the production of CFC MDIs.
The first step would be to start with the conversion of one product, which would likely be "BUTOVENT" Salbutamol BP. The conversion period would take about one year until KC Pharma finishes all the tests with technical assistance from UNIDO and equipment installation, staff training and obtaining a license and marketing authorization from the Ministry of Health of Syria.

In parallel the conversion of other products could start, therefore the whole period of conversion would take about 2 years provided that a technology provider selected by UNIDO would complete the task of new products formulation and 6 months testing at its premises. Therefore, one additional year needs to be taken into consideration.

6. Urgent conversion to HFA production is needed

For Syria and particularly for the health sector and environment the project is of a very high importance, because the Government of Syria need to urgently convert this company to non-CFC MDI production in order to provide locally produced cheaper MDIs for millions of asthma and COPD patients in Syria, specially those that have low income.

Another urgency to have HFA MDIs available in the country is the absence of imported inhalers in Syria and if they could be even available in the black market they are not affordable for most of Syrian population due to their higher price in comparison with those produced by KC Pharma. The low income of the majority of the people in Syria and in the Middle East region in general and the absence of good health insurance programs in most of the countries of the region characterize the pricing policy of KC Pharma with regard to the MDIs.

7. Number of non CFC MDI and DPI sold or distributed by active ingredients in Syria

An official document issued by the Ministry of Health stating that K.C Pharma is the only producer of MDI in Syria is attached.

According to the MOH's regulation "the Executive Instructions of Medical Drug Importation into Syria" it is stated in paragraph 2 that "…a company or a person cannot import any medicine into Syria if the same medicine is being produced in Syria…"(the MOH website: http://www.moh.gov.sy/arabic/drugs/fmain_13.htm).

However, if the medicine has another pharmaceutical form like, for example, DPI instead of MDI, the MOH allows other form of medicine to be imported.

With regard to import of MDIs or DPIs in Syria that there were only two types of imported inhalers and they were all in the DPI form.

Brand name	***Composition***	***Type***	***Manufacturer***	***Price, US$***	***Qty imported in 2007***
Seretide	Salmeterol 50 mcg Fluticasone 100 mcg 60 inhalations	DPI	GSK	N/A	1000 Pcs
Seretide	Salmeterol 50 mcg Fluticasone 250 mcg 60 inhalations	DPI	GSK	36.5	1000 Pcs

Brand name	***Composition***	***Type***	***Manufacturer***	***Price, US$***	***Qty imported in 2008***
VentolinDiscuss	Salbutamol 200 mcg, 60 inhalations	DPI	GSK	8.15	1500 Pcs

The difference in cost between Ventolin Discuss (Salbutamol 200 mcg), US$ 8.15 being imported by GSK and the similar product Butovent (Salbutamol 100 mcg, 200 inhalations), US$ 2.60 being produced by K.C. Pharma is US$ 5.55. The prices of DPIs from GSK are higher and prices of the similar MDI inhalers from K. C. Pharma are nearly 80% lower proving that it would not be possible to substitute the local MDIs with imported MDIs or DPIs.

There are no more official data available concerning imported CFC MDIs or HFC MDIs in Syria or DPIs as those items are likely sold only in an illegal way because their imports are prohibited in Syria, if locally manufactured and their figures are unknown to authorities but could be relatively small.

8. CFC use in 2008-2010

As the production and sales figures were revealed, the 40 % of the 2007 growth showed that the production and the consumption of CFC was increased dramatically over the last years and especially after KC Pharma entered new markets. Also an increase of population due to Iraqi refugees stipulated the growth of MDI

production at the company. An annual growth in production between 40 to 50 % is further expected in the short time.

9. National Transitional strategy

The present project preparation request is being submitted to enable not only the conversion to the HFA MDI production in Syria but also the smooth transition to
non-CFC MDIs in Syria, therefore phasing out CFC consumption in the MDI sector. In reviewing the data and information submitted, it was noted that there are serious variations in the supply of DPIs and MDIs produced and that the possible imports of CFC or HFA MDIs could be also prone to significant fluctuations. This may result in problems with availability of affordable MDIs that could affect patient care. It is due to the weakness of planning of anti-asthma/COPD medicines imports and because of this it impacts the patient population negatively, therefore there is a need to strengthen the system.

All the MDI products (CFCs and non-CFCs) are presently registered by Drug Administration of the Ministry of Health of Syria. The National strategy should address these tendencies in Syria associated with the increase of number of Asthma and COPD patients and analyze the dynamics of MDI imports and local production.
The National Transition Strategy will take in to account the current management approaches and prescribing habits associated with the treatment of Asthma and COPD in Syria. It will however also be mindful of current international “best practice” thinking associated with the management of those diseases. It will also make analyses of quantities of “reliever” and “preventing” medicines against asthma and COPD.
The national transition strategy will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of Ministry of Health, Drug Administration, health professionals, pharmaceutical companies/ association and the community.

The National Transitional Strategy will be developed as a part of the MDI project for K.C. Pharma.

Venezuela: Request for technical assistance to prepare CFC phase-out project in manufacture of Aerosol Metered Dose Inhalers (MDIs) and MDI transition strategy

1. Introduction

According to the decision of the 51/34 of the Executive Committee of the Montreal Protocol Multilateral Fund (MLF) concerning the formulation of MDI projects in the MDI producing countries the Executive Committee might consider the submission of requests for project preparation for the conversion of CFC-MDI production facilities on the understanding that must include a comprehensive justification from the country concerned for the need to receive assistance and should provide the following detailed information:

(i) name of nationally owned CFC-MDI manufacturing facilities, the data when the CFC production lines were established and the production capacity of each production line;
(ii) type of CFC-MDI products manufactured, active ingredients used, annual production output (units/yr);
(iii) growth patterns of CFC-MDI production over the past five years;
(iv) whether any of the CFC-MDI manufacturing plants were contemplating alternatives to CFC-MDI were contemplating alternatives to CFC-MDI and what those alternatives were;
(v) each production facility's plan for phasing out CFC consumption; and
(vi) the number of non-CFC MDIs and DPIs sold or distributed within the Party, by active ingredient, brand/manufacturer, and source.

On behalf of the Government of Venezuela, UNIDO is submitting a request for preparation of an MDI investment project dealing with the phase-out of 29.56 MT of CFCs at Laboratorios L.O. Oftalmi, C.A. (Calle 6 Zona Industrial La Urbina, Centro Empresarial R.S. Caracas 1070, Venezuela) and a transition strategy to phase-out CFC use in the MDI consumption sector. Data gathered during the NPP implementation showed that Venezuela manufacture about 2.0 million of CFC MDIs as well as import about 2.4 million of CFC and non CFC MDIs and even small quantities of DPIs.

The Table below shows imported CFC-based MDI, CFC-free MDIs and DPIs in Venezuela for the past three years.

CFC MDIs	761300	923000	1007200
DPIs	369700	470200	561400
HFA MDIs	592700	771300	854000
Total	**1723700**	**2164500**	**2422600**

It also showed that the trends of both CFC and non-CFC MDIs imports are increasing. The available data indicates that 1,135,000 units of such medical products were in use in 2005 and this number increased to 1,860,000 units in 2007. The quantity of CFC MDIs prevails on the CFC-free MDIs. There is also an overall concern from the Government of Venezuela and its health authorities on the MDI sub-sector particularly, since the incidences of chronic destructive pulmonary disease (COPD) and asthma are rising, Therefore, there is a need to ensure a steady supply of MDIs to meet these patients' needs. According to the survey conducted in 2003 in the Latin America the asthma prevalence was 7.1% in Venezuela and

this rate was the highest among the Latin American countries (Asthma control in Latin America: the Asthma Insights and Reality in Latin America (AIRLA) survey).

The requested funding for the development of an MDI transition strategy will establish a clear schedule for import of alternatives to CFC-MDIs in Venezuela. Regulations would also be needed that would promote and support the phase-out of these products, and a programme that would raise physician awareness and patient acceptance of alternatives to CFC-MDIs, as well as monitoring imports of MDIs. In support of their submission and based on decision 51/34, UNIDO indicated that the situation with regards to the manufacturer of MDIs and their non-CFC equivalents imports in Venezuela can be briefly described as follows:

(a) There is the production of CFC-based MDIs in Venezuela by the local producer, i.e. Laboratorios L.O. Oftalmi, C.A. at the actual capacity rate of about 2.0 million MDIs in 2007.

(b) There are CFC MDIs, HFA MDIs and DPIs in the market in Venezuela;

(c) There is a growing share of CFC MDI's in the market in 2005-2007;

(d) The imports of CFC MDIs during 2003-2005 were slowly increasing and imports of CFC MDIs went up to 50 percent of the market in 2007;

(e) Imports of HFA MDIs were also increasing from 2005 till 2007 up to 854,000 units; and

(f) There are also DPIs available in the market and their share is significant.

The objectives of the requested investment project would be to phase-out the use of CFC-11 and CFC -12 in the manufacture of Salbutamol, Beclomethasone Dipropionate and a combination of Salbutamol/ Beclomethasone Dipropionate Aerosol Metered Dose Inhalers (MDIs) at Laboratorios L.O. Oftalmi, C.A., which represents about 80% of the MDI consumption in the social security in Venezuela. In addition the successful completion of implementation of the project would result in the substitution of the Venticort, Salbutamol, Bucomax and Budecort MDIs being currently produced in Venezuela.

The conversion of Oftalmi to non-CFC based MDl products with the help of the Multilateral Fund will allow the company to keep prices at affordable level for low-income population and thus facilitating access to vital medication for millions of people. Thus, the conversion of its current CFC-based production line to a non-CFC based one is of strategic importance for the Government of Venezuela owing to its contribution to the protection of both, the population's health, in particular the millions of people suffering under respiratory diseases, and the environment.

The CFC National Phase out Plan was approved by the 42nd ExCom in April 2004. The NPP will phase out the total CFC demand of 2,032 ODP tones in Venezuela estimated for 2003. The Plan aims at phasing-out all the remaining consumption of Annex A, Group I CFCs in Venezuela over the period of 2004 – 2010 and it will enable the Government of Venezuela to totally phase-out the CFC consumption by January 01, 2010 except the CFC usage chiller servicing. A series of investment, non-investment, and technical support activities are planned to achieve this target in the foam and refrigeration sectors. The relatively low consumption of CFCs for the MDI production of 20.72 ODP tones in 2003 out of 2,032 ODP tones in comparison with a NPP estimate of 16.0 ODP tones in the aerosol and solvent sectors (2003) was not properly addressed.

2. CFC production lines were established and the production capacity of each production line

Laboratorios L.O. Oftalmi, C.A is the only CFC-based MDl producer in Venezuela. The company, with 100% national ownership, was founded in 1985 and it has been producing CFC MDls since 1991. 80% of Oftalmi's production covers the supply to the Venezuelan Health System. The remaining 20 % goes to the free market of the country. Laboratorios L.O. Oftalmi, C.A is a specialized pharmaceutical company established for ophthalmic products.

Laboratorios L.O. Oftalmi, C.A.

Company address:

Laboratorios L.O. Oftalmi, C.A.
Calle 6 Zona Industrial La Urbina, Centro Empresarial R.S. Caracas 1070, Venezuela
Tel: +58-212-2424904 / 2424747 / 2424774 / 2426304 Ext 112
Fax: +58-212-2424424 / 2424656
Website: http://www.oftalmi.com
Owner: Mr. Sebastián Ruscica

To this date Laboratorios L.O. Oftalmi, C.A. is the only manufacturer of Metered Dose Inhalers in Venezuela. The production line for MDI was set in 1991 for one product only. Nowadays the company manufactures six different MDI products, all of which are of high quality. The MDIs, which are being produced by Laboratorios L.O. Oftalmi, C.A. were originally conceived and developed by the Research and Development Department of the company using the pharmaceutical experience of the world-leading MDI producers. All of the MDIs were approved for manufacture and sales in the country by the local sanitary authority "Instituto Nacional de Higiene Rafael Rangel", a department of the Ministry of Health.

Presently there is no licensing agreement and/or technical assistance contract between Laboratorios L.O. Oftalmi, C.A. and any other company.

Since January 1st 2007 there has been no local production of CFC propellants in Venezuela and Laboratorios L.O. Oftalmi, C.A. has had to rely on local suppliers and distributors and their current stock. The company was assured by the Ministry for Environment that this stock would be sufficient to cover 2007 and 2008 at the current consumption levels of Laboratorios L.O. Oftalmi, C.A.

2.1. Type of MDI Products manufactured at Oftalmi

The six MDI products are manufactured at Laboratorios L.O. Oftalmi, C.A. They are:
Venticort, Duovent, Cromospray, Salbutamol, Beclomax and Budecort. Beclomethasone dipropionate is produced in two strength 50 µg and 200 µg. Laboratorios L.O. Oftalmi, C.A. currently consumes both CFC-11 and CFC-12 in the manufacture of aerosol MDIs. The CFC-

11 is used for the preparation of a "slurry suspension " of the active ingredient to facilitate filling the precise quantity into the open aerosol MDI container, after which the MDI aerosol container is closed with the aerosol metering valve, and the CFC-12 that acts as the aerosol "propellant" is injected into the aerosol container under pressure through the metering valve. This production process applies for all CFC aerosol products according to Secretaría de Salud (Mexican Health Agency). Specifications for the following products are:

Commercial Brand	**Generic Name**	**Active per Dose (valve actuation)**	**Total actuation volume (mcl)**	**Total Nº of doses per canisterº**
Venticort	Salbutamol (Albuterol / Beclomethasone dipropionate	100 µg / 50 µg	63	200
Duovent (*)	Fenoterol hydrobromide / Ipratropium bromide	50 µg / 20 µg	63	200
Cromospray (*)	Cromolyn sodium	5 mg	120	112
Salbutamol	Salbutamol (albuterol)	100 µg	63	200
Beclomax	Beclomethasone dipropionate	50 µg	63	200
Budecort	Beclomethasone dipropionate	200 µg	50	100

The MDI manufacturing facilities at Laboratorios L.O. Oftalmi, C.A. are well managed and all production has strict quality control of all stages of the procurement and storage of materials and components, as well as the manufacturing process fully meeting the requirements of the Good Manufacturing Practices (GMPs). This is required for effective medication delivery and use by asthma patients.

2.2. MDI Production Capacity at Oftalmi

The actual capacity of production of Metered Dose inhalers is about 2,000,000 units per year on a basis of 8 working hours per shift, one shift per day, 5 days per week and a total of 225 working days per year. This is an estimated capacity based on company’s past and current production statistics. The installed production capacity is about 5,000,000 units per year. These estimates do not take into account a small research and development line, which has a laboratory scale capacity.

At present time, the customer’s demand is covered with about 2 millions units/year, but in 2008 the demand could be increased due to population growth and governmental social policies.

The details of the MDIs being produced at Oftalmi is given in the table below:

Metered Dose Inhalers manufactured by Oftalmi using CFC propellants

Commercial Brand	Generic Name	Active per Dose (valve actuation)	Total actuation volume (mcl)	Total Nº of doses per canisterº	Propellants
Venticort	Salbutamol (Albuterol / Beclomethasone dipropionate	100 µg / 50 µg	63	200	11, 12
Duovent (*)	Fenoterol hydrobromide / Ipratropium bromide	50 µg / 20 µg	63	200	11, 114
Cromospray (*)	Cromolyn sodium	5 mg	120	112	12, 114
Salbutamol	Salbutamol (albuterol)	100 µg	63	200	11, 12
Beclomax	Beclomethasone dipropionate	50 µg	63	200	11, 12
Budecort	Beclomethasone dipropionate	200 µg	50	100	11, 12

(*) These products were discontinued in May 2004 because of the unavailability of propellant 114. Efforts were made in trying to reformulate the products using combinations of 11 and 12 with no success.

Annual production output per product (in units per year)

Product	2003	2004	2005	2006	2007
Venticort	261.086	363.514	368.640	463.112	785.419
Duovent (*)	63.220	66.910	45.315	0	0
Cromospray (*)	55.949	58.425	8.014	0	0
Salbutamol	596.111	593.054	732.649	555.787	546.296
Beclomax	294.378	325.415	319.616	141.663	423.680
Budecort	281.563	286.112	273.487	147.106	193.622
Totales	**1.552.307**	**1.693.430**	**1.747.721**	**1.307.668**	**1.949.017**

Annual production output (in units)

Year	Total annual production, units
2003	**1.552.307**
2004	**1.693.430**
2005	**1.747.721**
2006	**1.307.668**
2007	**1.949.017**
Total	**8.250.143**

2.3. Manufacturing description and product specifications

The aerosol filling system mainly consists of a mixing/homogenizing vessel, a rotary index based pressure filling machine and a recirculating system for filling a "concentrated mix" (low vapour pressure propellant + active + excipients) and a single piston propellant filling pump.

The mixing vessel (1) has a maximum capacity of about 120 kg and has a double blade rotating agitator (3) with a homogenizing device at the end of its shaft (4). It can provide a maximum of 70 rpm for main agitator and 3600 rpm for homogenizer. Its maximum nominal working pressure is 10 bar but it has attached a safety valve set to 7 bar (2). This vessel has a freon-cooled coiled jacket, which can provide the temperature up to –20ºC to the inner side and also has the capability of working at the room temperature (Manufacturer: ***Greatide Industrial Co., Ltd. 5th Fl. Nº9, Sec 3, Jen Air Road, Taipei 10651***, Taiwan ROC).

The filling machine (8.) is an integrated monobloc rotary index pressure filling machine that has a crimping head and a filling head (***Terco, Inc.459 Camden Drive, Bloomingdale, IL.USA***). This machine is an all-pneumatic driven controlled equipment and it does not have any electrical or electronic component other than conveying system (9). It requires 25,50 cfm@80-100 psi oil-free filtered compressed air.

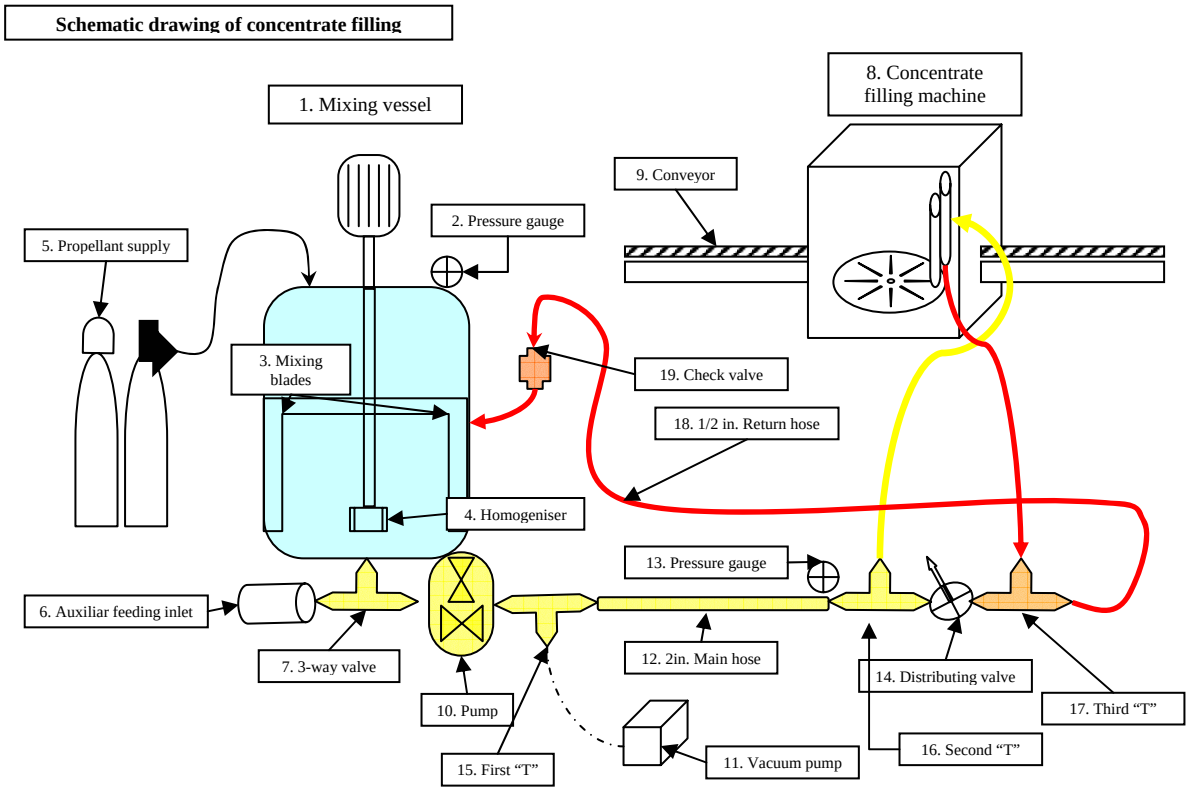
The recirculating system consists of a twin-wing rotary piston pump (10) attached to the bottom of the tank. This pump transfers the mix through a 1 feet long/2 in. i.d. Tygon high-pressure hose (12) to a double T-valve system, which distributes the product to feed the machine or to recirculate it to the tank again.

Pictured in yellow is the outgoing way the concentrate runs through when is pumped away from the tank to the filling machine: there is a 3-way valve (7) attached to the bottom of the tank to allow to feed additional propellant or active adjustments through an auxiliary feeding inlet (6), when the system is pressurized and turned on. Then there is a pump and after that a first "T" (15) with a safety valve through which a vacuum (11) is applied into all the system before turning it on. When the product is running inside the recirculating system it goes through a 2 inches i.d. high-pressure hose to a second "T" (16) where is driven to the filling machine (8) or to the third "T" depending on the situation whether a distributing valve between them is open or closed.

Once the product mix is ready in the mixing vessel a vacuum is applied inside the distributing system, pump (10) is turned on and distributing valve is set to open position; it allows products free run through the whole distribution system and back to the mixing vessel without reaching the filling machine. When the distributing valve is almost fully closed, pressure at point 13 (see a drawing below) reaches 80-120 psi, the product goes to the machine´s feeding inlet hose, machine is turned on, and then the filling process starts.

Between each machine's two strokes the system opens a valve set, which allows the product to go back to the recirculating system and then back to the vessel (pictured in red is the returning path).

This production line is considered as completely unfit for production of HFA MDIs, since construction materials in contact with product and/or propellant are not suitable or compatible. Different working temperatures and pressure ranges also influentiate the expected outcomes.

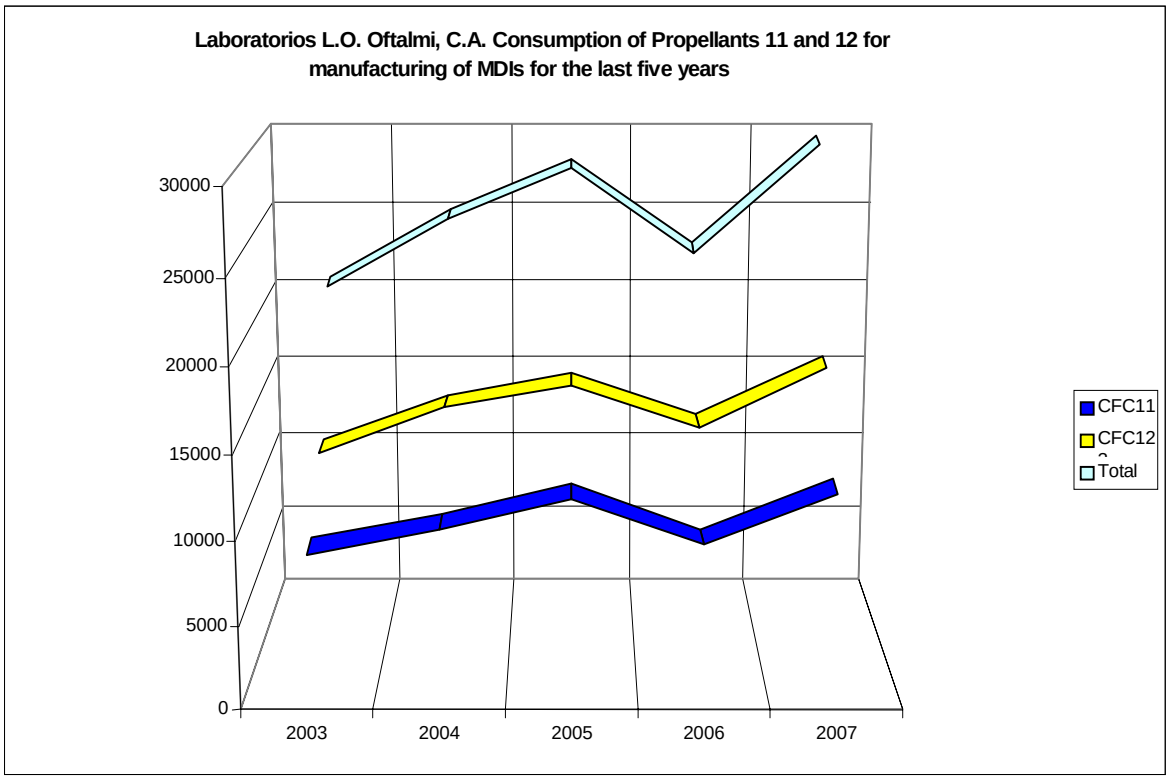


Note: *Numbers are referred to "Schematic drawing of concentrate filling machine" drawing below.*

2.4. Annual Consumption of CFC Propellants used in Manufacturing of MDIs

The next table below displays the consumed quantities of CFC propellants for manufacturing MDIs during the past three years.

Year	***Propellant 11***	***Propellant 12***	***Total consumption of CFCs (in Kg)***
2003	*8450*	*12266*	*20716*
2004	*9904*	*15055*	*24959*
2005	*11714*	*16391*	*28105*
2006	*8989*	*13864*	*22853*
2007	*12106*	*17454*	*29560*
Total	***51163***	***75030***	***105477***
Average	***10232***	***15006***	***26369***



3. Existing Equipment at Oftalmi

The major equipment is:

- mixing/homogenizing vessel
- rotary index based pressure filling machine
- recirculating system for filling a "concentrated mix" (low vapour pressure propellant + active + excipients) and a single piston propellant filling pump.

The mixing vessel has a maximum capacity of about 120 kg and has a double blade rotating agitator with an homogenizing device at the end of its shaft. It can provide a maximum of 70 rpm for main agitator and 3600 rpm for homogenizer. Its maximum nominal working pressure is 10 bar but it has attached a safety valve set to 7 bar. This vessel has a freon-cooled coiled jacket which can provide until –20ºC to the inner side and has the capability of working at room temperature also (Manufacturer: ***Greatide Industrial Co., Ltd. 5th Fl. Nº9, Sec 3, Jen Air Road, Taipei 10651***, Taiwan ROC).

The filling machine is an integrated monobloc rotary index pressure filling machine that has a crimping head and a filling head (***Terco, Inc.459 Camden Drive, Bloomingdale, IL.USA***). This machine is an all-pneumatic driven controlled equipment and it does not have any electrical or electronic component other than a conveying system.

3. New Machinery for HFA products

This paragraph represents a summary of the MDI manufacturing facility that has been designed for use with the HFA formulation. This aerosol MDI manufacturing facility can operate at approximately 40 - 50 cans per minute giving an annual output of about 3 million cans/year based on 230 working days/single shift operation. This was used to determine the

level of capital cost that Laboratorios Oftalmi would need taking into consideration specific requirements.

This machine is capable of filling HFA propellant only or HFA product suspensions or solutions under pressure through the aerosol valve.

Equipment Required: The final list of equipment to produce HFA MDIs including the one currently used for CFC MDI is as follows:

Equipment Required for HFA
1. Mixing Vessel and Macromat Line for Filling MDI with HFA Suspensions/Solutions with Commissioning and installation.
2. Spray Checking Machine.
3. New HFC storage propellant system (15 tons).

Equipment in place or not needed
1. Air Filters.

The following table shows a list of required machinery to be procured and its cost estimate to fulfill the requirements of production of new MDIs using HFA propellants.

Equipment item	**Cost in CHF**
Feeding Plate	1.320,00
Conveyor Belt 6 m	17.890,00
Macromat P 2045 /014 Pharma	114.236,00
Valve inserter P 2058	16.650,00
Vacuum crimper P 2002/021 and Vacuum Pump P14019/004	30.905,00 F
Diagraphm Filler P 2079	44.160,00
Vacuum Pump P14019/004 Type MLD 50 Viton	5.670,00
Double Diagraphm pum P2089/001	41.450,00
Propellant Pump P2008/012	12.350,00
Propellant Filter P 2011/021	33.103,00
Valve Transport System X02047-038	41.040,00
Valve Sorting System Type RNA	38.140,00
Valve Elevator	22.250,00
Checkweigher OCS HC-IS 2000-2	65.510,00
Pressure Mixing Vessel and accesories	205.080,00
Accesories and complements	9.310,00
Packing	2.500,00
FOB European Seaport	5.600,00
Seafreight costs	6.565,00
Insurance	3.300,00
Total Price CIF la Guaira / Venezuela	717.029,00

This equipment is manufactured by:
Pamasol Willi Mäder AG
Driesbüelstrasse 2 Postfach 157

CH-8808 Pfäffikon SZ Switzerland
Tel: +41 (0) 55 417 40 36

Costs associated to legal or regulatory affairs, training, consultancy, marketing, storage and distribution and weight average cost of capital have not been included in estimated figures above.

5. Plan for phasing out CFC consumption in the production facility

5.1. Replacement Technology, HFA formulations and materials

To implement the selected replacement technologies, Laboratorios Oftalmi, will require technology transfer from one, or more, established multinational enterprises that have experience in the manufacture of CFC-Free MDIs using alternative technologies and that have the right to transfer such technology without infringement of any intellectual property related to either the drug molecule, the method of formulation, the design of the metering valve or actuator, or the filling process.

The selected replacement technologies require different production processes than those used at present for the existing CFC-MDI products:

a) Salbutamol HFA-MDI
b) Beclomethasone Dipropionate HFA-MDI
c) Salbutamol/ Beclomethasone Dipropionate HFA-MDI

A. Salbutamol HFC-MDI

For the conversion of Salbutamol CFC-MDI to HFC-MDI based on a suspension of Salbutamol or Salbutamol Sulphate in HFC-134a Laboratorios Oftalmi requires completely different production equipment.

The HFC-134a will replace both CFC-11 and CFC-12 in the CFC-MDI formulation, because HFC-134a is a gas at atmospheric pressure this will involve the preparation of a slurry Salbutamol or Salbutamol Sulphate suspension in HFC-134a in a pressure vessel. Precisely measured amounts of the Salbutamol/HFC-134a "suspension slurry" will then be injected under pressure through a modified metering valve into the already closed aerosol MDI container. A further injection of HFC-134a will be made into the aerosol container through the metering valve to clear any of the Salbutamol/HFC-134a "suspension slurry" from the valve. Also, due the HFC-134a is more abrasive than CFCs, the machine has need different characteristics.

B. Beclomethasone Dipropionate HFC-MDI

Both 50 mcg and 200 mcg doses Beclomethasone Dipropionate MDIs need to be solutions. The medicament drug suspension is manufactured basically by similar technology as used for the CFC MDI version, but the CFC-11 used as the liquid phase of the suspension and to solubilise the surfactant, as well as to modify the final vapour pressure of the MDI formulation, is replaced by ethyl alcohol (ethanol). However, due to the different solubility properties of ethanol and CFC-11 the surfactant has to be replaced by a new surfactant chemical. This suspension is then, metered in the aluminium monobloc container. The propellant CFC-12 is replaced by HFC-134a. As the spray/particle size characteristics of the ethanol/HFC-134a MDI formulation are different to those of the CFC MDI version, the valve

and actuator have to be redesigned to achieve the required spray and particle size characteristics for efficacious dosage. Some products use HFC-227ea as the propellant instead of HFC-134a.

C. **A combination of Salbutamol and Beclamethasone dipropionate** 200 Dose, 100 µg + 50 µg/ dose label claim (or an alternate combination of a Beta agonist and steroid that are acceptable from the perspective of market needs and technology transfer costs).

The combination of Salbutamol and Beclamethasone dipropionate conversion is based on a suspension of combination of Salbutamol and Beclamethasone dipropionate in HFC-134a or HFC-227 or in mixture will replace both CFC-11 and CFC-12 in the CFC-MDI formulation. The process will involve the preparation of a slurry drug suspension in HFC propellant in a pressure vessel. Precisely measured amounts of the combination of Salbutamol and Beclamethasone dipropionate /HFC propellant will be injected under pressure through a modified metering valve into the already closed aerosol MDI container. A further injection of HFC will be made into the aerosol container through the metering valve to clear any of the combination of Salbutamol and Beclamethasone dipropionate suspension from the valve.

At present time there are not licensing, technical assistance, or technology transfer agreements relating to HFC-MDI manufacture.

For the CFC conversion projects the retrofit of existing CFC manufacturing equipment is not possible because of the poor compatibility of the HFC-134a or HFC-227 with existing machinery seals and because of the new preparation and method of filling. As a result, completely new CFC-free MDI manufacturing facilities are required.

The transition process from CFC-MDIs to CFC-free MDIs in Laboratorios Oftalmi requires that for a period of some time there will a need for production of both CFC-MDIs, and CFC-free MDIs. The transition process will be carried on in two steps: first to convert Salbutamol CFC-MDI aerosol suspension to a CFC-free MDI aerosol suspension. In the second step, Beclomethasone Dipropionate and combination of Salbutamol and Beclamethasone dipropionate will be converted and the rest of CFC will be eliminated.

5.2. Project duration period

After Project approval for Salbutamol (First step)

• Plant adaptation and equipment installation and product test: 11 months.
• Product Registration to produce in Venezuela: 3 months.
• Starting production at commercial level: 1 month.

For Beclometasone plus certifications and reports (Second step) 6 months more for:

• Product Registration to produce in Venezuela: 3 months
• Starting production at commercial level: 1 month.
• Verifications certifications and reports: 2 months.

For Salbutamol/Beclometasone (mixture) plus certifications and reports (Third step) 6 months more for:

• Product Registration to produce in Venezuela: 3 months

• Starting production at commercial level: 1 month.
• Verifications certifications and reports: 2 months.

Preliminary estimation for the project duration is 3 years.

5.3. Urgent conversion to HFA MDI production is needed

For Venezuela, and particularly for the Ministry of Environment this project is of a very high importance, because the Government of Venezuela needs to urgently achieve conversion of CFC MDI to non-CFC MDI production in order to provide cheaper MDIs for millions of asthma and pulmonary disease patients in Venezuela, especially those with a low income.

Asthma is a public health problem and a well-recognized urban chronic respiratory disease in Venezuela. Acute asthma ranks second in morbidity after the "viral syndrome" and ahead of diarrhea and other diseases with more than a million acute asthma crises per at the Ministry of Health ambulatory services. This network system attends to the majority (70-80% or more) of a predominant young and urban – around 80% -population (24 million inhabitants; 40% under 15 years of age) living in crowded urban dwellings in variable conditions of poverty. On other hand a shortage of specialized asthma clinics across the country rounds up a focused and prevailing general approach centered on acute care. The International Study for Asthma and Allergies in Children (ISAAC) Venezuela 2003 informs of nearly one million urban persistent asthmatics (6-13 years of age) and hence the need for long-term anti-inflammatory medications. There is an overall concern from health authorities in Venezuela about the MDI supply, since the prevalence of chronic destructive pulmonary disease (COPD) and asthma is rising.

6. Transition Strategy for the elimination MDIs with CFCs and the introduction of the replacement CFC MDIs in Venezuela

6.1. Number of non-CFC MDI and DPI sold or distributed by active ingredient, brand/manufacturer, and source

The Table below shows the quantities of CFC and non-CFC MDIs as well as DPIs imported into the country by active ingredient, brand/manufacturer, and generic name in the past three years.

Quantities of CFC and non-CFC MDIs and DPIs imported into the country

Brand name	Manufacturer	Drug	Class	Generic name	2005	2006	2007
FORADIL	NOVARTIS	Formoterol	R03A3	DPI	88000	106000	111300
FLUIR	VALMORCA		R03A3	DPI		5100	12400
SEREVENT	GLAXO SMITH KLINE	Salmeterol	R03A3	HFA	4900	4600	4100
FORMOTEC	PHARMACEUTICAL GROUP	Formoterol	R03A3	HFA		500	1100
SALBUTAN	GLAXO SMITH KLINE	Salbutamol	R03A4	HFA	205000	261900	412000
SALBUROL	VALMORCA	Salbutamol	R03A4	HFA	94600	143800	138500
SALBUTAMOL	L.O.	Salbutamol	R03A5	HFA	142600	154300	
SALBUMED	MEDIFARM	Salbutamol	R03A4	HFA		11500	74400

ASTHALIN HFA	PHARMACEUTICAL GROUP	Salbutamol	R03A4	CFC		51800	109600
ASTHALIN ECO	PHARMACEUTICAL GROUP	Salbutamol	R03A4	HFA		20100	
SALBUTAMOL	MEDIFARM	Salbutamol	R03A4	CFC	23800	1300	
BUDECORT	L.O.	Budesonide	R03D1	CFC	19000	33700	41500
PULMICORT TURBOHALER	ASTRA ZENECA	Budesonide	R03D1	DPI	92600	95200	109900
PULMICORT AERO	ASTRA ZENECA	Budesonide	R03D1	HFA	56100	60900	75100
ALVESCO	GRUNENTAL	Ciclesonide	R03D1	CFC		8500	21800
MIFLONIDE	NOVARTIS	-	R03D1	DPI	18400	22200	26200
BUDESONIDA	MEDIFARM	Budesonide	R03D1	CFC	20400	32400	40900
ASMANEX	SCHERING P.	Mometasone	R03D1	DPI	1700	9300	9100
PULMOLET	LETI	Budesonide	R03D1	CFC	4000	11700	10600
FLIXOTIDE	GLAXO SMITH KLINE	Fluticasone	R03D1	HFA	4900	4000	6200
BECLOSIL	MEDIFARM	Beclamethasone	R03D1	CFC	4500	6500	
BECLOFORTIL	MEDIFARM	Beclamethasone	R03D1	CFC	1800	1900	1800
SYCORT	PHARMACEUTICAL GROUP	Ciclesonide	R03D1	HFA		100	2600
SERETIDE	GLAXO SMITH KLINE	Salmeterol+ Fluticasone	R03F1	DPI	31200	38700	48600
SERETIDE	GLAXO SMITH KLINE	Salmeterol+Fluticasone	R03F1	HFA	83300	94300	105600
VENTIDE	GLAXO SMITH KLINE	Salbutamol+ Beclamesone	R03F1	CFC	387600	415200	360200
FORASEQ	NOVARTIS	Formoterol	R03F1	DPI	42600	56500	73800
SYMBICORT	ASTRA ZENECA	Budesonide+ Formetorol	R03F1	DPI	83800	100500	115500
VENTICORT	L.O.	Salbutamol	R03F1	CFC	111500	135800	171400
BUTOSOL	MEDIFARM	Beclamethasone	R03F1	CFC	25700	37200	48900
AEROCORT	PHARMACEUTICAL GROUP	Beclamethasone	R03F1	HFA		13500	28600
BECLOMET	VALMORCA	Beclamethasone	R03F1	CFC	100	7200	14200
SEROFLO	PHARMACEUTICAL GROUP	Salmeterol+Fluticosone	R03F1	HFA			2700
FORACORT	PHARMACEUTICAL GROUP	Salmeterol+ Budesonide	R03F1	HFA			3100
BERODUAL	BOERINGER ING	Ipratropium Bromide+Fenoterol	R03G4	CFC	149400	167800	174500
COMBIVENT	BOERINGER ING	Ipratropium Bromide + Salbutamol	R03G4	CFC	13500	12000	11800

SPIRIVA	BOERINGER ING	Tiotropium Bromide	R03G3	DPI	11400	36700	54600
ALOVENT	BOERINGER ING	-	R03G4	HFA	1300	1800	
TOTAL					**1723700**	**2164500**	**2422600**

Annual CFC- MDIs, non-CFC MDIs and DPI production				
Propellant	2005		2006	2007
CFC	761300		923000	1007200
DPI	369700		470200	561400
HFA	592700		771300	854000
Total	**1723700**		**2164500**	**2422600**

Both CFC and non-CFC MDIs imports are increasing in Venezuela. 1,135,000 units of such medical products were in use in 2005 and this number increased to 1,860,000 units in 2007. The quantity of CFC MDIs is still above CFC-free MDIs.

6.2. National Transitional Strategy

The national transition strategy as a part of the MDI conversion project will take into account sufficient time and resources for the education of health professionals and the patients and their families in the substitution of CFC MDIs, which should be part of a National Programme of Asthma. This requires a coordination and participation of the Ministry of Health, physicians, health professionals, pharmaceutical companies/association and the community.

The education and sensitising campaign for the introduction of new products (HFA MDIs) will therefore be both necessary and challenging in this situation. Considering the above-mentioned elements the implementation of an education programme involving health professionals, patients, their families and the community from the very beginning becomes a priority, led by the Ministry of Health and Medical Education.

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