Global Alliance for Vaccines and Immunisation (GAVI)

APPLICATION FORM FOR COUNTRY PROPOSALS

For Support to:

Immunisation Services, Injection Safety
and New and Under-Used Vaccines

Revised 9th April 2008

Please return a signed copy of the document to:
GAVI Alliance Secretariat; c/o UNICEF, Palais des Nations, 1211 Geneva 10, Switzerland.

Enquiries to: Dr Ivone Rizzo, irizzo@gavialliance.org or representatives of a GAVI partner agency. All documents and attachments must be in English or French.

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Executive Summary

The Ministry of Public Health and Sanitation has been very interested in the introduction of a vaccine against streptococcus pneumonia for a very long time because of the significant morbidity & mortality that this bacterium causes to the children of Kenya.

However, because of the high market costs of the two vaccine preparations available globally, the Government of Kenya could not afford to procure it for the national immunization schedule.

Despite the compelling evidence showing high cost effectiveness and the potential of reducing the burden of pneumonia disease, the vaccine has not been introduced in Kenya due to the high market costs and the unavailability of Development Partners offering support for the vaccine to GoK. It is against this background that the offer from GAVI for a co-financing procurement arrangement was so readily embraced and the Ministry of Public Health and Sanitation submitted an expression of interest for this support and has now completed the formal application form.

While we recognize that the 7-valent pneumococcal conjugate vaccine is not the right fit for our known sero-type prevalence, we believe it is the ***best*** fit under the currently available global products because: -

- It covers 60% of our pneumococcal disease burden
- It can be administered to the highest risk age group – i.e. those less than 2 years old. Kenya's infant mortality rate is 77 per 1000 live births

Again the opportunity for the pneumococcal conjugate vaccine in its current presentation (in single dose vials) has come when our cold-chain equipment is undergoing rehabilitation and expansion. We see this as not only a challenge but also an opportunity.

The challenge is that we will have to expand our cold chain at all levels, and to order and distribute all vaccines more frequently. The opportunity is that the cold chain can be objectively overhauled.

In the preparation of this document, we noted data inconsistencies in some of our official reports, such as the Annual Progress Report 2006 (APR 2006) and the Joint Reporting Form 2005. We used APR 2006 data whenever there were discrepancies because it had a data covering multiple years. We have thus included APR 2006 as document 11. It is for this reason that in our forecast for 2009 – 2013 the DPT1 and DPT3 coverage are equal, yet in reality, drop-outs are expected.
We have also included data for 2013, which is not covered under any document, by increasing with a factor of 1.7%, consistent with the existing trend.
However, these inconsistencies will be rectified partly in our current APR 2007 and comprehensively during the revision of our cMYP planned for later this year.

It is our sincere hope that our application will be favourably considered, as we believe that this vaccine will significantly reduce the suffering of thousands of Kenyan parents of having their children debilitated or killed by streptococcus pneumonia disease.

The attainment of Millennium Development Goal No.4 will also be accelerated.

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2. Signatures of the Government and National Coordinating Bodies

Government and the Inter-Agency Coordinating Committee for Immunisation

The Government of **Kenya** would like to expand the existing partnership with the GAVI Alliance for the improvement of the children under 5 years routine immunisation programme of the country, and specifically hereby requests for GAVI support for **Pneumococcal vaccine**

The Government of **Kenya** commits itself to developing national immunisation services on a sustainable basis in accordance with the comprehensive Multi-Year Plan presented with this document. The Government requests that the GAVI Alliance and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Table N° 6.5 of page 19 of this application shows the amount of support in either supply or cash that is required from the GAVI Alliance. Table N° 6.4 of page 19 of this application shows the Government financial commitment for the procurement of this new vaccine (NVS support only).

Minister for Public Health and Sanitation:

Signature: ……

Name**: Hon Beth W. Mugo**

Date: ……

Minister for Finance:

Signature: ……

Name: **Hon Amos Kimunya**

Date: ……

National Coordinating Body - Inter-Agency Coordinating Committee for Immunisation:

We the members of the Child Health ICC[1] met on the **10th April 2008** to review this proposal. At that meeting we endorsed this proposal on the basis of the supporting documentation which is attached.

- The endorsed minutes of this meeting are attached as DOCUMENT NUMBER: ……

Name/Title	Agency/Organisation	Signature

In case the GAVI Secretariat has queries on this submission, please contact:

Name: Dr S.K Sharif

Title: Head, Promotive and Preventive Health Services

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Address: Box 30016 -00100

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Nairobi

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Kenya

[1] Inter-agency coordinating committee or Health sector coordinating committee, whichever is applicable.

The GAVI Secretariat is unable to return documents and attachments to individual countries. Unless otherwise specified, documents may be shared with the GAVI partners and collaborators.

The Inter-Agency Coordinating Committee for Immunisation

Agencies and partners (including development partners and CSOs) supporting immunisation services are co-ordinated and organised through an inter-agency coordinating mechanism (ICC/HSCC). The ICC/HSCC are responsible for coordinating and guiding the use of the GAVI ISS and NVS support. Please provide information about the ICC/HSCC in your country in the spaces below.

Profile of the ICC

Name of the ICC: Child Health ICC

Date of constitution of the current ICC: 4TH November 2004

Organisational structure (e.g., sub-committee, stand-alone): Stand-alone

Frequency of meetings: Every two months routinely but extraordinary meetings on need basis

Composition:

Function	Title / Organization	Name
Chair	Head, Promotive and Preventive Health Services	Dr S.K. Sharif
Secretary	Head, Division of Child Health	Dr Anna Wamae
Members	• Head, Division of Vaccines & Immunization – Ministry of Public Health and Sanitation • Head Division of Nutrition • National Coordinating Agency for Population Development • Head Of Health Section - Unicef • WHO–Kenya Child-Health Advisor • WHO Inter-country Support Team EPI Advisor • Division of Reproductive Health • Division of Malaria Control. • Ministry of Education Science & Technology • Ministry of Home Affairs – Children's Department • Ministry of Gender, Culture, Sports & Social Services • DfID Health Advisor • DANIDA • JICA • USAID • African Medical & Research Foundation • Supreme Council of Kenyan Muslims • Christian Health Associations of Kenya • Kenya Catholic Secretariat for Health and Family Life • University of Nairobi – Dept of Paediatrics • Kenyatta National Hospital Dept. of Paediatrics • Kenya Medical Training Colleges Kenya Medical Research Institute – Centre for Clinical Research	• Dr. Tatu Kamau • Mrs Rosemary Ngaruro • Dr. Kizito • Ms. Marilyn McDonagh • Dr. Assumpta Mureithi • Dr. Messeret Eshetu

Major functions and responsibilities of the ICC/HSCC:

- Act as a link between various Child Health working groups, the respective offices/officers within the Ministry of Public Health and Sanitation and the Joint ICC (JICC) as well as other ICCs and their working groups.

- Advise on the temporary or permanent establishment of Child Health issues, assist in their operations, coordinate and monitor their progress, contribute to their agendas and liaise so as to create effective synergies.

- Advise the Ministry of Public Health and Sanitation on priority areas of CH services, quality assessments, emerging CH issues among other things

- Assist in the organization of special CH occasions
- Reviewing how research findings can best be utilized
- Resource mobilization for the Child Health agenda

Three major strategies to enhance the CH-ICC's role and functions in the next 12 months:

1.Expanding to include Civil Society

2. Regularizing meetings to monthly

3. Strengthening the Secretariat in mobilizing members attendances

3. Immunisation Programme Data

Please complete the tables below, using data from available sources. Please identify the source of the data, and the date. Where possible use the most recent data, and attach the source document.

- Please refer to the Comprehensive Multi-Year Plan for Immunisation (or equivalent plan), and attach a complete copy (with an executive summary) as DOCUMENT NUMBER 3

- Please refer to the two most recent annual WHO/UNICEF Joint Reporting Forms on Vaccine Preventable Diseases and attach them as DOCUMENT NUMBERS 1 and 2.

- Please refer to Health Sector Strategy documents, budgetary documents, and other reports, surveys etc, as appropriate.

Table 3.1: Basic facts for the year **2008** (the most recent; specify dates of data provided)

	Figure	Date	Source
Total population	35,112,181	2008	CBS Estimates
Infant mortality rate (per 1000)	77	2003	Kenya Demographic and Health Survey
Surviving Infants*	1,340,080	2008	Annual Progress Report , Calculated from CBS Estimates
GNI per capita (US$)	705	2006	Economic Survey 2007
Percentage of GDP allocated to Health	1.7	2007/2008	Ministry of Public Health and Sanitation facts and Figures 2008
Percentage of Government expenditure on Health	6.4	2006/2007	Ministry of Public Health and Sanitation facts and Figures 2008

* Surviving infants = Infants surviving the first 12 months of life

Please provide some additional information on the planning and budgeting context in your country:

Please indicate the name and date of the relevant planning document for health
National Health Sector Strategic Plan (NHSSP) II 2005-2010 and implemented under Annual Operation Plans (AOPs).

Is the cMYP (or updated Multi-Year Plan) aligned with this document (timing, content etc)
Planning cycle for cMYP was based on calendar year (Jan-Dec) while NHSSP II was aligned to financial year (July-June). cMYP has now been aligned to the financial year.

Please indicate the national planning budgeting cycle for health
The national planning cycle is July – June while the cMYP was planned from January – December. While the budget for cMYP was aligned to the national cycle, planning was not aligned but has been adjusted to align with Minnistry's planning cycle as from Annual Operation Plan 3 (2007/2008)

Please indicate the national planning cycle for immunisation
Starting from July 2007, the national immunisation planning cycle has been aligned to the government planning cycle that starts from 1st July 2007 to 30th June 2008

Table 3.2: Current Vaccination Schedule: Traditional, New Vaccines and Vitamin A Supplement *(cMYP page 10)*

Vaccine *(do not use trade name)*	**Ages of administration** *(by routine immunisation services)*	**Indicate by an "x" if given in:**		**Comments**
		Entire country	**Only part of the country**	
BCG	At birth	X		
OPV	At birth, 6wk, 10wk and 14wk	X		
DPT-HepB-Hib	6wk, 10wk and 14wk	X		
Measles	9 months	X		
Yellow Fever	9 months		X	Given only in four districts (Baringo, Keiyo, Koibatek and Marakwet) at high risk of yellow fever disease
TT	Pregnant women	X		Given in pregnancy under the 5TT schedule.
Vitamin A	6m,12m,18m,24m,30m,36m,42 m,48m,54m and 60m	X		Also given to mothers within six weeks after delivery

Table 3.3: Trends of immunisation coverage and disease burden
(as per last two annual WHO/UNICEF Joint Reporting Form on Vaccine Preventable Diseases)

Trends of immunisation coverage (in percentage)						Vaccine preventable disease burden		
Vaccine		Reported		Survey		Disease	Number of reported cases	
		2005	2006	2005	2006		2005	2006
BCG		85	92			Tuberculosis*	ND	39093
DTP	DTP1	86	90			Diphtheria	ND	ND
	DTP3	77	80			Pertusis	ND	ND
Polio 3		71	77			Polio	0	2
Measles (first dose)		70	77			Measles	153	1847
TT2+ (Pregnant women)		72	73			NN Tetanus	56	38
Hib3		77	80			Hib **	6	3
Yellow Fever		39	47			Yellow fever	0	0
HepB3		77	80			HepB sero-prevalence*	ND	ND
Vit A supplement	Mothers (<6 weeks post-delivery)	ND	ND					
	Infants (>6 months)	50	51					

* If available
** Note: JRF asks for Hib meningitis

If survey data is included in the table above, please indicate the years the surveys were conducted, the full title and if available, the age groups the data refers to:

Not Applicable

Table 3.4: Baseline and annual targets *(cMYP page 15)*

Number		Baseline and targets					
		Base year 2005	**Year 1 2006**	**Year 2 2007**	**Year 3 2008**	**Year 4 2009**	**Year 5 2010**
Births		1,374,185	1,402,126	1,427,113	1,452,346	1,477,822	1,503,537
Infants' deaths		96,265	108,384	110,315	112,266	114,236	116,223
Surviving infants		1,277,920	1,293,742	1,316,798	1,340,080	1,363,586	1,387,314
Pregnant women		1,374,185	1,402,126	1,427,113	1,452,346	1,477,822	1,503,537
Target population vaccinated with BCG		1,174,712	1,293,995	1,398,572	1,423,300	1,448,266	1,473,466
BCG coverage*		85	92	98	98	98	98
Target population vaccinated with OPV3		988,866	1,036,453	1,250,958	1,273,076	1,295,407	1,317,948
OPV3 coverage**		77	80	95	95	95	95
Target population vaccinated with DTP3***		988,866	1,036,453	1,250,958	1,273,076	1,295,407	1,317,948
DTP3 coverage**		77	80	95	95	95	95
Target population vaccinated with DTP1***		1,104993	1,158,005	1,250,958	1,273,076	1,295,407	1,317,948
Wastage[2] rate in base-year and planned thereafter		25%	25%	25%	25%	25%	25%
Target population vaccinated with **3rd dose** of Pneumococcal vaccine……..						1,295,407	1,317,948
Pneumococcal vaccine Coverage**						95%	95%
Target population vaccinated with **1st dose** of Pnemoccoal vaccine……..						1,295,407	1,317,948
Wastage[1] rate in base-year and planned thereafter						5%	5%
Target population vaccinated with **1st dose** of Measles		893,976	990,768	1,185,118	1,206,072	1,227,228	1,248,582
Target population vaccinated with **2nd dose** of Measles		NA	NA	NA	NA	NA	NA
Measles coverage**		70	77%	90%	90%	90%	90%
Pregnant women vaccinated with TT2+		994,253	1,022,779	1,213,047	1,234,495	1,256,149	1,278,007
TT+ coverage****		72%	73%	85%	85%	85%	85%
Vit A supplement	Mothers (<6 weeks from delivery)	ND	ND	50%	50%	50%	50%
	Infants (>6 months)	50%	51%	60%	65%	70%	75%
Annual DTP Drop out rate [(DTP1-DTP3)/DTP1] x100		10	10	8	5	5	10
Annual Measles Drop out rate (for countries applying for YF)		NA	NA	NA	NA	NA	NA

* Number of infants vaccinated out of total births
** Number of infants vaccinated out of surviving infants
*** Indicate total number of children vaccinated with either DTP alone or combined
**** Number of pregnant women vaccinated with TT+ out of total pregnant women

[2] The formula to calculate a vaccine wastage rate (in percentage): [(A – B) / A] x 100. Whereby: A = The number of doses distributed for use according to the supply records with correction for stock balance at the end of the supply period; B = the number of vaccinations with the same vaccine in the same period. For new vaccines check **table α** after Table 7.1.

Table 3.5: Summary of current and future immunisation budget *(or refer to cMYP pages 6,22,43)*

Cost Category	Estimated costs per annum in US$ (,000)					
	Base year	Year 1 2006	Year 2 2007…	Year 3 2008…	Year 4 2009…	Year 4 2010…
Routine Recurrent Cost	**US$**	**US$**	**US$**	**US$**	**US$**	**US$**
Traditional vaccines	1,800	2,476	2,531	2,698	2,785	2,876
New and underused vaccines	14,360	16,620	17,122	20,726	49,887	45,735
Injection supplies	664	1,508	1,701	2,007	2,541	2,742
Personnel						
Salaries of full-time NIP health workers (immunization specific)	188,004	186	190	194	197	201
Per-diems for outreach vaccinators/mobile teams/supervision	2,619	3,934	5,304	5,654	6,017	6,391
Transportation	41	43	45	47	50	52
Maintenance and overhead	614	720	951	1,275	1,326	1,048
Training	156	791	78	115	81	83
IEC/social mobilization	36	73	75	77	77	79
Disease surveillance	40	92	94	96	98	100
Programme management	334	342	350	358	376	394
Other	0	0	56	0	59	0
Subtotal Recurrent Costs	**208,668**	**26,785**	**28,497**	**33,247**	**63,494**	**59,701**
Routine Capital Cost						
Vehicles	0	0	0	0	0	153
Cold chain equipment	0	445	1,896	2,670	27	100
Other capital equipment	2	151	97	92	93	95
Subtotal Capital Costs	**2**	**596**	**1993**	**2762**	**120**	**348**
Campaigns						
Campaigns						
Polio	1,019	235	778			
Measles	800	6,033			6,510,714	
Yellow Fever						
MNT	0	0	0	0	0	0
Other campaigns	0	7,060	3,049	3,181	1,575	
Subtotal Campaign Costs	**1,819**	**13,328**	**3,827**	**3,181**	**6,512,289**	**0**
GRAND TOTAL	**210,489**	**40,709**	**34,317**	**39,190**	**6,575,903**	**60,049**

Please list in the tables below the funding sources for each type of cost category (if known). Please try and indicate which immunisation program costs are covered from the Government budget, and which costs are covered by development partners (or the GAVI Alliance), and name the partners.

Table 3.6: Summary of current and future financing and sources of funds *(or refer to cMYP)*

Cost Category	Estimated financing per annum in US (,000)						
	Funding Source	Base year 2005	Year 1 2006	Year 2 2007…	Year 3 2008 …	Year 4 2009…	Year 4 2010…
Routine Recurrent Cost		**US**	**US**	**US**	**US**	**US**	**US**
Vaccines (routine vaccines only)							
Traditional vaccines	GOK	1,800	2,476	2,531	2,698	2,785	2,876
New and underused vaccines	GAVI	14,360	16,620	17,122	20,726	49,887	45,735
Injection supplies	GOK	664	1,508	1,701	2,007	2,541	2,742
Personnel							
Salaries of full-time NIP health workers (immunization specific)	GOK	188	186	190	194	197	201
Per-diems for outreach vaccinators/mobile teams/supervision	GOK	2,619	3,934	5,304	5,654	6,017	6,391
Transportation	GOK	41	43	45	47	50	52
Maintenance and overhead	GOK	614	720	951	1,275	1,326	1,048
Training	Gap	156	791	78	115	81	83
IEC/social mobilization	GOK	36	73	75	77	77	79
Disease surveillance	WHO	40	92	94	96	98	100
Programme management	Gov	334	342	350	358	376	394
Other		0	0	56	0	58,631	0
Subtotal Recurrent Costs	**GOK/UNICEF/ WHO**	**20,852**	**26,785**	**28,497**	**33,247**	**122,066**	**59,701**
Routine Capital Cost							
Vehicles		0	0	0	0	0	153
Cold chain equipment	GOK	0	445	1,896	2,670	27	100
Other capital equipment	GOK	2	151	97	92	93	95
Subtotal Capital Costs	**GOK**	**2**	**596**	**1993**	**2762**	**120**	**348**
Campaigns							
Polio	GOK/UNICEF/ WHO/	1,019	235	778			
Measles	UNICEF/WHO	800	6,033			6,511	
Yellow Fever							
MNT		0	0	0	0	0	0
Other campaigns		0	7,060	3,049	3,181	1,575	
Subtotal Campaign Costs		**1,819**	**13,328**	**3,827**	**3,181**	**8,086**	**0**
GRAND TOTAL		**22,673**	**40,709**	**34,317**	**39,190**	**130,272**	**60,049**

4. Immunisation Services Support (ISS)

Please indicate below the total amount of funds you expect to receive through ISS:

Table 4.1: Estimate of fund expected from ISS

	Base Year (cMYP)	2007	Year 1 2008	Year 2 2009	Year 3 2010	Year 4 2011	Year 5 2012
DTP3 Coverage rate	77	95	95	95	95	95	95
Number of infants reported / planned to be vaccinated with DTP3 (as in Table 3.4)	988,866	1,250,958	1,273,076	1,295,407	1,317,948	1,340,551	1,363,428
Number of *additional* infants that annually are reported / planned to be vaccinated with DTP3	50,567	214,505	22,118	22,331	22,541	22,603	22,877
Funds expected (20 per additional infant)	1,011,340	4,290,100	442,360	446,620	450,820	452,060	457,540

* Projected figures
** As per duration of the cMYP

If you have received ISS support from GAVI in the past, please describe below any major lessons learned, and how these will affect the use of ISS funds in future.

Please state what the funds were used for, at what level, and if this was the best use of the flexible funds; mention the management and monitoring arrangements; who had responsibility for authorising payments and approving plans for expenditure; and if you will continue this in future.

Major Lessons Learned from Phase 1	Implications for Phase 2
1. Delays in approval for internal disbursement	Need to establish project expenditure review committee within the Ministry to ensure integrated approach to interventions
2. Challenges of monitoring funds received outside government system	• Need for a structured Financial Management Information System (FMIS) acceptable to the government • Possible channel of disbursement to SWAp
3. Central planning for funds, limiting districts' utilization for specific needs	Incorporation into Ministry Planning cycle
4. Weak monitoring arrangement	Need for a structured Financial Management Information System (FMIS)

If you have not received ISS support before, please indicate:

a) when you would like the support to begin:
Not Applicable

b) when you would like the first DQA to occur:
Not Applicable

c) how you propose to channel the funds from GAVI into the country: ***Not Applicable***

d) how you propose to manage the funds in-country: ***Not Applicable***

e) who will be responsible for authorising and approving expenditures: ***Not Applicable***

- Please complete the banking form (annex 1) if required

5. Injection Safety Support

- Please attach the National Policy on Injection Safety including safe medical waste disposal (or reference the appropriate section of the Comprehensive Multi-Year Plan for Immunisation), and confirm the status of the document: DOCUMENT NUMBER……

- Please attach a copy of any action plans for improving injection safety and safe management of sharps waste in the immunisation system (and reference the Comprehensive Multi-Year Plan for Immunisation). DOCUMENT NUMBER…….

Table 5.1: Current cost of injection safety supplies for routine immunisation

Please indicate the current cost of the injection safety supplies for routine immunisation.

	Annual requirements		*Cost per item (US)*		*Total Cost (US)*
Year	*Syringes*	*Safety Boxes*	*Syringes*	*Safety Boxes*	
20…					

Table 5.2: Estimated supply for safety of vaccination with …….. vaccine

(Please use one table for each vaccine BCG(1 dose), DTP(3 doses), TT(2 doses) [1], Measles(1 dose) and Yellow Fever(1 dose), and number them from 6.1 to 6.5)

		Formula	Year 1 20…	Year 2 20…	Year 3 20…	Year 4 20…	Year 5 20…
A	Number of children to be vaccinated [2]	#					
B	Percentage of vaccines requested from GAVI [3]	%					
C	Number of doses per child	#					
D	Number of doses	*A x B/100 x C*					
E	Standard vaccine wastage factor [4]	*Either 2.0 or 1.6*					
F	Number of doses (including wastage)	*A x B/100 x C x E*					
G	Vaccines buffer stock [5]	*F x 0.25*					
H	Number of doses per vial	#					
I	Total vaccine doses	*F + G*					
J	Number of AD syringes (+ 10% wastage) requested	*(D + G) x 1.11*					
K	Reconstitution syringes (+ 10% wastage) requested [6]	*I / H x 1.11*					
L	Total of safety boxes (+ 10% of extra need) requested	*(J + K) / 100 x 1.11*					

Not Applicable

[1] GAVI supports the procurement of AD syringes to deliver two doses of TT to pregnant women. If the immunisation policy of the country includes all Women in Child Bearing Age (WCBA), GAVI/The Vaccine Fund will contribute to a maximum of two doses for Pregnant Women (estimated as total births)
[2] To insert the number of infants that will complete vaccinations with all scheduled doses of a specific vaccine.
[3] Estimates of 100% of target number of children is adjusted if a phased-out of GAVI/VF support is intended.
[4] A standard wastage factor of 2.0 for BCG and of 1.6 for DTP, Measles, TT, and YF vaccines is used for calculation of INS support
[5] The buffer stock for vaccines and AD syringes is set at 25%. This is added to the first stock of doses required to introduce the vaccination in any given geographic area. Write zero under other years. In case of a phased introduction with the buffer stock spread over several years, the formula should read: [F – number of doses (incl. wastage) received in previous year] * 0.25.
[6] It applies only for lyophilized vaccines; write zero for other vaccines.

- If you do not intend to procure your supplies through UNICEF, please provide evidence that the alternative supplier complies with WHO requirements by attaching supporting documents as available.

6. New and Under-Used Vaccines (NVS)

Please give a summary of the cMYP sections that refer to the introduction of new and under-used vaccines. Outline the key points that informed the decision-making process (data considered etc):

As one of the national priorities, capacity to determine and set policies and priorities for new vaccines will be strengthened. This will include

1. Development of a systematic process for the introduction of new or under-used vaccines
2. Technical review
3. Ensuring appropriate disease surveillance to support disease burden study
4. Advocacy with ICC, financing ministry, NGOs/partners to create financial support for new vaccines with focus on of introduction of new vaccines
5. Develop policy and guidelines use of new vaccines
6. Introduction of new vaccines appropriate for the country.

The decision to introduce pneumococcal vaccine was based on the following

1. Opportunity offered by GAVI for support in introduction of the vaccine.
2. Documented pneumococcal disease burden in the country
3. Interest of the government to achieve Millennium Development Goal 4
4. The fact that close to 60% of the local serotypes of Streptococcus pneumoniae were covered by the available vaccine

Please summarise the cold chain capacity and readiness to accommodate new vaccines, stating how the cold chain expansion (if required) will be financed, and when it will be in place. Please use attached excel annex 2a (Tab 6) on the Cold Chain. Please indicate the additional cost, if capacity is not available and the source of funding to close the gap

There are 4 cold rooms available at the national level (1 freezer room and 3 Positive temperatures cold rooms). There are 11 freezers and 12 refrigerators/freezers which are used as backups to the existing cold rooms.

The total positive vaccine storage capacity for the cold rooms and the refrigerators at the national level is 30.4 m^3.

In 2008 the vaccine storage capacity is adequate since now new vaccine will be introduced. Two additional cold rooms each with 12m^3 capacity have already ordered as part of the Government's effort to expand the vaccines storage facilities.

With proposed introduction of the pneumococcal vaccine in 2009, three additional cold rooms each with 14 m^3 capacity will be required by the end of 2008. An additional cold room will be required in 2011 but needs to be procured and installed before the end of 2010.

At the regional level, three cold rooms each 12m^3 have been ordered by using government funds. These have been procured and will be installed by the end 2008. In addition, 12 refrigerators each 110litres be required in 2008, five in 2009, thirty two in 2010 and nine in 2011.

There are about 150 districts stores which will require an additional 333 refrigerators preferably MK304 by end of 2008 to accommodate the new pneumococcal vaccines.

There about 3200 immunizing facilities most of them using RCW 42/50 EG. These equipments will not have adequate capacity to store the new vaccines. In view of this an additional 1000 refrigerators of 55 litres will be required by before the introduction of the new vaccine.

The Ministry of Public Health and Sanitationand Sanitation has allocated funds that will be able to cater for these extra cold chain equipments within a period of three years.

Table 6.1: Capacity and cost (for positive storage) (*Refer to Tab 6 of Annex 2a or Annex 2b)*

		Formula	Year 1 2008	Year 2 2009	Year 3 2010…	Year 4 2011	Year 5 2012
A	Annual ***positive*** volume requirement, including new vaccine (specify:_____) (litres or m3)[3]	*Sum-product of total vaccine doses multiplied by unit packed volume of the vaccine*	72.18m^3	353.22m^3	364.54m^3	396.36m3	409.09m^3
B	Annual ***positive*** capacity, including new vaccine (specify:_____) (litres or m3)	#	30.4 m^3	54.4 m^3	96.4 m^3	96.4m^3	110.4m^3
C	Estimated minimum number of shipments per year required for the actual cold chain capacity	*A / B*	2.37	6.49	3.74	4.1	3.72
D	Number of consignments / shipments per year	*Based on national vaccine shipment plan*	4	4	4	4	4
E	Gap (if any)	*((A / D) - B)*	-12.35m^3	12m^3	14m^3	0	14m^3
F	Additional cold rooms required		2	3	0	1	0
G	Cold room capacity		12 m^3	14 m^3	0	14m^3	0
H	Cost in (USD)		100,000	150,000	0	50,000	0
I	Comments		Ordered and is to be installed in 2008	To be ordered to and installed by December 2008	Adequate capacity if 2008 procurement is	To be ordered and delivered in 2010	

Please briefly describe how your country plans to move towards attaining financial sustainability for the new vaccines you intend to introduce, how the country will meet the co-financing payments, and any other issues regarding financial sustainability you have considered (refer to the cMYP):

Three strategies will be used to attain financial sustainability.

1. Mobilization of extra resources: This will be achieved through increased funding for EPI through MTEF. This has already been done to cater for the co-financing of the pneumococcal vaccine. Local corporate have potential to fund some EPI activities. The cMYP will be shared with non-traditional partners to expand funding base for vaccines. Efforts will be made to engage them and create interest in them to support immunization activities.
2. Improve program effectiveness: Capacity of health workers to effectively manage and utilize available resources will be enhanced. Vaccine wastage will be monitored and efforts made to minimize it. This is expected to save resources that can be used to procure more vaccines. Capacity for program monitoring and evaluation will be improved. The cMYP will be updated regularly to ensure that it takes into consideration the existing challenges and that it takes advantage of emerging sources of funding.

3. Improve reliability of funding: Negotiations will be held with key partners such as WHO, UNICEF and JICA for funding pledges beyond one year.

[3] Use results from table 5.2. Make the sum-product of the total vaccine doses row (I) by the unit packed volume for each vaccine in the national immunisation schedule. All vaccines are stored at positive temperatures (+5°C) except OPV which is stored at negative temperatures (-20°C).

Table 6.2: Assessment of burden of relevant diseases *(if available)*:

Disease	Title of the assessment	Date	Results
Pneumococcal Meningitis Pneumonia and Other diseases	WHO Global Burden of Pneumococcal Disease (WHO Geneva, in progress)	2007	No's of **cases** in Kenya in 2007 were estimated as 1,307 meningitis, 153,539 pneumonia and 8,647 other diseases.
Pneumococcal deaths from Meningitis Pneumonia etc	WHO Global Burden of Pneumococcal Disease (WHO Geneva, in progress)	2007	No's of **deaths** in Kenya in 2007 were estimated as 845 meningitis, 15,344 pneumonia and 370 other diseases.
Bacteremic pneumococcal disease (inpatients)	Bacteremia among Children Admitted to a Rural Hospital in Kenya. Berkley et al. N Engl J Med 2005; 352:39-47	2005	In a Kenyan District Hospital observed incidence rates were 241,213 and 111/100,000 in children aged <1yr, <2yrs and <5yrs respectively.
Bacteremic pneumococcal disease (outpatients)	Incidence of clinically significant bacteraemia in children who present to hospital in Kenya. Brent et al. Lancet 2006; 367:482-8	2006	Incidence rates for presentation with clinically significant pneumococcal bacteraemia in children under 5 years was 436/100,000/yr.
Proportion of *S. pneumoniae* serotypes in 7 valent PCV	Epidemiology of invasive pneumococcal disease among children in Kilifi District, Kenya. 5th ISPPD meeting Alice Springs, 2006	2006	Among 669 invasive paediatric isolates cultured at Kilifi District Hospital in 1994-2005 7-valent PCV serotype coverage (incl. type 6A) was 43%. Among children 6-29m, it was 60%.
Proportion of *S. pneumoniae* serotypes in 7 valent PCV	Network for Surveillance of Pneumococcal Disease in the East Africa Region. (www.netspear.org)	2004-2006	The vaccine coverage of 7-valent PCV (including type 6A) was 44.4% of 365 strains isolated in 6 Kenyan hospitals from children of all ages.
Radiologically-confirmed pneumonia	Community based surveillance for admission with radiologically confirmed pneumonia in children aged <5 yrs in Kilifi Ignas J et al - in progress	2006-2007	In a population of 45,000 children aged <5 years, the incidence of admission to hospital with WHO defined radiologically confirmed pneumonia was 556/100,000/yr
Deaths from pneumonia	Pneumonia. The forgotten killer of children. UNICEF/WHO	2006	Estimated no. of deaths from pneumonia in children <5 years was 32,000 in 2004. Approx half of these deaths are likely to be pneumococcal.

If new or under-used vaccines have already been introduced in your country, please give details of the lessons learnt from storage capacity, protection from accidental freezing, staff training, cold chain, logistics, drop out rate, wastage rate etc., and suggest solutions to address them:

Lessons Learned	Solutions / Action Points
Storage capacity: It is very crucial to assess the existing vaccines storage capacity at all levels, from the national to the immunization facility i.e. Health centres and dispensaries to ensure there is adequate capacity before placing the order	**Vaccine storage assessment** be carried out at least ***one year before*** the introduction of any new vaccines to give time to reorganize the cold chain and procure new equipment if necessary
Protection from freezing: This was managed by prior training of health workers, ensuring that the cold chain equipments thermostats were adjusted to positive temperatures (+2^{O}c	**Provision of adequate equipment and ensure that health workers are trained** as close as possible to the introduction of the new vaccines followed by supportive supervision.

to +8 ^{O}C) , ensuring the use of vaccine trays in all top opening equipments and use of pre-conditioned icepacks	
Drop out rate Being a new vaccine there was very low drop-out because of high awareness about Hepatitis B	**Ensure wide publicity about the new vaccines** and the specific benefits in terms of the diseases prevented. This should be done through the both electronic and print media
Wastage rate; It was below 10% in most of the health facilities since it was a 2 dose vial although some vials were yielding more than 2 doses depending on the administration from different health workers	**To safe guard any wastage** at any level of administration and ensuring that health workers use the right techniques to reconstitute and administer the vaccine.

Please list the vaccines to be introduced with support from the GAVI Alliance (and presentation):

7-valent Pneumococcal conjugate vaccine, single dose formulation

First Preference Vaccine

As reported in the updated cMYP, the country plans to introduce *pneumococcal* vaccinations, using *conjugate* vaccine, in *single dose per vial in liquid* form.

Please refer to the excel spreadsheet Annex 2a or Annex 2b (for Rotavirus and Pneumo vaccines) and proceed as follows:

- Please complete the "Country Specifications" Table in Tab 1 of Annex 2a or Annex 2b, using the data available in the other Tabs: Tab 3 for the commodities price list, Tab 5 for the vaccine wastage factor and Tab 4 for the minimum co-financing levels per dose[4].

- Please summarise the list of specifications of the vaccines and the related vaccination programme in Table 6.3 below, using the population data (from Table 3.4 of this application) and the price list and co-financing levels (in Tables B, C, and D of Annex 2a or Annex 2b).

- Then please copy the data from Annex 2a or 2b (Tab "Support Requested") into Tables 6.4 and 6.5 (below) to summarize the support requested, and co-financed by GAVI and by the country.

- Please submit the electronic version of the excel spreadsheets Annex 2a or 2b together with the application

[4] *Table D1 should be used for the first vaccine, with tables D2 and D3 for the second and third vaccine co-financed by the country*

Table 6.3: Specifications of vaccinations with new vaccine

Vaccine: PCV	*Use data in:*		**Year 1 2009**	**Year 2 2010**	**Year 3 2011**	**Year 4 2012**	**Year 4 2013**
Number of children to be vaccinated with the third dose	*Table 3.4*	#	1,295,407	1,317,948	1,340,551	1,363,428	1,386,695
Number of children to be vaccinated with additional 2 doses during one-time catch-up for under fives in Kilifi & Bondo districts			299,104	-	-	-	
Target immunization coverage with the third dose	*Table 3.4*	#	95	95	95	95	95
Number of children to be vaccinated with the first dose	*Table 3.4*	#	1,295,407	1,317,948	1,340,551	1,363,428	1,386,695
Estimated vaccine wastage factor	*Annex 2a or 2b Table E - tab 5*	#	1.05	1.05	1.05	1.05	
Country co-financing per dose *	*Annex 2a or 2b Table D - tab 4*		0.15	0.15	0.20	0.20	0.20

* Total price pre dose includes vaccine cost, plus freight, supplies, insurance, fees, etc

Table 6.4: Portion of supply to be co-financed by the country (and cost estimate, US)

		Year 1 2009	**Year 2 2010**	**Year 3 2011**	**Year 4 2012**	**Year 5 2013**
Number of vaccine doses	#	246,700	201,700	274,500	278,200	280,200
Number of AD syringes	#					
Number of re-constitution syringes	#					
Number of safety boxes	#	2,750	2,250	3,050	3,100	3,125
Total value to be co-financed by country		765,500	625,500	848,500	863,000	877,500

Table 6.5: Portion of supply to be procured by the GAVI Alliance (and cost estimate, US)

		Year 1 2009	**Year 2 2010**	**Year 3 2011**	**Year 4 2012**	**Year 5 2013**
Number of vaccine doses	#	4,854,000	3,967,700	3,966,100	4,034,800	4,106,300
Number of AD syringes	#					
Number of re-constitution syringes	#					
Number of safety boxes	#	53,900	44,050	44,025	44,800	45,600
Total value to be co-financed by GAVI		25,052,000	20,477,500	20,567,000	20,967,000	21,324,500

- Please refer to http://www.unicef.org/supply/index_gavi.html for the most recent GAVI Alliance Vaccine Product Selection Menu, and review the GAVI Alliance NVS Support Country Guidelines to identify the appropriate country category, and the minimum country co-financing level for each category.

Second Preference Vaccine

If the first preference of vaccine is in limited supply or currently not available, please indicate below the alternative vaccine presentation

Not Applicable

- Please complete tables 6.3 – 6.4 for the new vaccine presentation

- Please complete the excel spreadsheets Annex 2a or Annex 2b for the new vaccine presentation and submit them alongside the application.

Procurement and Management of New and Under-Used Vaccines

a) Please show how the support will operate and be managed including procurement of vaccines (GAVI expects that most countries will procure vaccine and injection supplies through UNICEF):

Vaccine and injectable supplies will be procured through UNICEF procurement division.
Distribution and management will be like in all EPI vaccines currently offered, according to the existing Ministry of Public Health and Sanitation distribution system

b) If an alternative mechanism for procurement and delivery of supply (financed by the country or the GAVI Alliance) is requested, please document:

- *Other vaccines or immunisation commodities procured by the country and description of the mechanisms used.*
- *The functions of the National Regulatory Authority (as evaluated by WHO) to show they comply with WHO requirements for procurement of vaccines and supply of assured quality.*

Not Applicable

c) Please describe the introduction of the vaccines (refer to cMYP)

One time introduction in the whole country that will be integrated into the existing schedule (refer to the Introduction Plan - attachment number 9.)

d) Please indicate how *funds* should be transferred by the GAVI Alliance (if applicable)

GAVI contribution to the country should be given as vaccines rather than cash. The ISS funds and GAVI awards should be paid thorugh the Permanent Secretary, Ministry of Public Health and Sanitation.

e) Please indicate how the co-financing amounts will be paid (and who is responsible for this)

The payment will be to GAVI through UNICEF as indicated in the Introduction Plan (attachment no. 9)

The Permanent Secretary, Ministry of Public Health and Sanitationand Sanitation, will make payments annually. Payments will be in US dollars in or before October of each year as per the existing pentavalent vaccine co-payment arrangement.

f) Please outline how coverage of the new vaccine will be monitored and reported (refer to cMYP)

Monitoring and reporting will be through

-Progressive administrative coverage data
-Annual Progress Report to GAVI
-National Coverage surveys e.g. KDHS, programme commissioned surveys.
-Programme assessment
-Periodic Data Quality Assessment (DQA)

New and Under-Used Vaccine Introduction Grant

Table 6.5: calculation of lump-sum

Year of New Vaccine introduction	N° of births (from table 3.4)	Share per birth in US	Total in US
2009	1,477,822	0.30	443,346.6

Please indicate in the tables below how the one-time Introduction Grant[5] will be used to support the costs of vaccine introduction and critical pre-introduction activities (refer to the cMYP).

Table 6.6: Cost (and finance) to introduce the first preference vaccine (US)

Cost Category	Full needs for new vaccine introduction	Funded with new vaccine introduction grant
	US	US
Training	***100 000***	***100 000***
Social Mobilization, IEC and Advocacy	***100 000***	***100 000***
Cold Chain Maintenance	***78 000***	***78 000***
Vehicles and Transportation		
Programme Management	***50 000***	***50 000***
Surveillance and Monitoring	***50 000***	***50 000***
Human Resources		
Waste Management		
Technical assistance		
Documentation tools	***50 123***	***50 123***
Cold Chain Equipment	***206 440***	***15 213.6***
Other (please specify)		
Other (please specify)		
Total	***634 573***	***443 346.6***

[5] The Grant will be based on a maximum award of $0.30 per infant in the birth cohort with a minimum starting grant award of $100,000

- Please complete the banking form (annex 1) if required

Please complete a table similar to the one above for the second choice vaccine (if relevant) and title it **Table 6.7: Cost (and finance) to introduce the second preference vaccine (US)**

7. Additional comments and recommendations from the National Coordinating Body (CHILD HEALTH-ICC)

8. Documents required for each type of support

Type of Support	Document	DOCUMENT NUMBER	Duration *
ALL	WHO / UNICEF Joint Reporting Form (last two)	***1,2***	*2005,2006*
ALL	Comprehensive Multi-Year Plan (cMYP)	***3***	*2006-2010*
ALL	Endorsed minutes of the National Coordinating Body meeting where the GAVI proposal was endorsed	***N/A***	
ALL	Endorsed minutes of the Child Health-ICC meeting where the GAVI proposal was discussed	***4***	
ALL	Minutes of the three most recent ICC/HSCC meetings	***5,6,7***	
ALL	ICC workplan for the forthcoming 12 months	***8***	
Injection Safety	National Policy on Injection Safety including safe medical waste disposal (if separate from cMYP)	***NA***	
Injection Safety	Action plans for improving injection safety and safe management of sharps waste (if separate from cMYP)	***NA***	
Injection Safety	Evidence that alternative supplier complies with WHO requirements (if not procuring supplies from UNICEF)	***NA***	
New and Under-used Vaccines	Plan for introduction of the new vaccine (if not already included in the cMYP) **Included**	***9***	
New and under-used vaccines	Experiences in the introduction of new vaccines in Kenya – *the DPT-HepB-Hib experience*	***10***	

** Please indicate the duration of the plan / assessment / document where appropriate*

ANNEX 1

Banking Form

SECTION 1 ***(To be completed by payee)***

In accordance with the decision on financial support made by the Global Alliance for Vaccines and Immunisation dated . . . . . , the Government of . . . . . hereby requests that a payment be made, via electronic bank transfer, as detailed below:

Name of Institution: *(Account Holder)*	
Address:	
City – Country:	
Telephone No.:	**Fax No.:**
Amount in USD:	(To be filled in by GAVI Secretariat) **Currency of the bank account:**
For credit to: ***Bank account's title***	
Bank account No.:	
At: ***Bank's name***	

Is the bank account exclusively to be used by this program? **YES ( ) NO ( )**

By whom is the account audited? .....

Signature of Government's authorizing official:
By signing below, the authorizing official confirms that the bank account mentioned above is known to the Ministry of Finance and is under the oversight of the Auditor General.

Name:	.....	**Seal:**
Title:	.....	
Signature:	.....	
Date:	.....	
Address and Phone Number:		

SECTION 2 *(To be completed by the Bank)*

FINANCIAL INSTITUTION		CORRESPONDENT BANK (*In the United States)*
Bank Name:		
Branch Name:		
Address:		
City – Country:		
Swift code:		
Sort code:		
ABA No.:		
Telephone No.:		
Fax No.:		
Bank Contact Name and Phone Number:		

I certify that the account No. . . . . is held by *(Institution name)* . . . . . .at this banking institution.

The account is to be signed jointly by at least …… *(number of signatories)* of the following authorized signatories:	**Name of bank's authorizing official:**
1 Name: ..... **Title:**	**Signature:** ..... **Date:** .....
2 Name: ..... **Title:**	**Seal:**
3 Name: ..... **Title:**	
4 Name: ..... **Title:**	

COVERING LETTER

(To be completed by UNICEF representative on letter-headed paper)

TO: GAVI Alliance – Secretariat
Att. Dr Julian Lob-Levyt
Executive Secretary
C/o UNICEF
Palais des Nations
CH 1211 Geneva 10
Switzerland

On the …… I received the original of the BANKING DETAILS form, which is attached.

I certify that the form does bear the signatures of the following officials:

	Name	Title
Government's authorizing official	.....	.....
Bank's authorizing official	.....	.....

Signature of UNICEF Representative:

Name .....

Signature .....

Date .....