

APPLICATION FORM FOR COUNTRY PROPOSALS

For Support for: Meningococcal A conjugate vaccine

Submitted by The Government of

(NIGERIA)

Revised February 2011

(for the 2011 round of applications)

Please submit the Proposal to: proposals@gavialliance.org

Enquiries at this email address or through representatives of a GAVI partner agency. The Proposal and attachments must be submitted in English or French.

Please ensure that the application has been received by the GAVI Secretariat on or before the day of the deadline.

The GAVI Secretariat is unable to return submitted documents and attachments to countries. Unless otherwise specified, documents will be shared with the GAVI Alliance partners and the general public.

Acronyms

AD Auto-disable (syringes)

ADIP Accelerated development and introduction programmes

APR Annual progress report BCG Bacille Calmette-Guerin

cMYP Comprehensive multi-year plan for immunisation

CSO Civil society organisation

DTP3 Diphtheria-tetanus-pertussus, 3rd dose

DQA Immunisation data quality audit

EPI Expanded programme on immunisation

GDP Gross domestic product
GNI Gross national income

HSCC Health Sector Coordination Committee

Hep B Hepatitis B

Hib Haemophilus influenzae type b

ICC Inter-Agency Co-ordination Committee for Immunisation

ICG International Coordinating Group

INS Injection safety support

IRC Independent Review Committee ISS Immunisation services support

JRF WHO / UNICEF Joint Reporting Form on Vaccine Preventable Diseases

LDC UN Least Developed Country
MDG Millennium development goals
MenA Meningococcal conjugate vaccine A

MoF Ministry of Finance MoH Ministry of Health

NRA National Regulatory Authority

NVS New and underused vaccine support

Phase 1 GAVI Alliance Phase 1 Support (2000-2005)
Phase 2 GAVI Alliance Phase 2 Support (2006-2010)
SAGE WHO Strategic Advisory Group of Experts

SWAp Sector Wide Approach

TT Tetanus Toxoid UN United Nations

UNFPA United Nations Population Fund UNICEF United Nations Children's Fund WHO World Health Organization

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1 Executive Summary

Nigeria suffers a large burden of Meningococcal Meningitis with regular outbreaks occurring between November and April, the majority of which is caused by serotype A. The last epidemic occurred in 2009, when over 50,000 cases were reported.

Following the successful piloting of "MenAfriVac" vaccine in Mali, Niger and Burkina Faso, Nigeria is keen to roll out a preventative immunization campaign in order to eliminate epidemics of meningococcal meningitis due to serotype A (MenA). The campaign is expected to yield substantial public health, social and economic benefits. In addition, minimizing MenA transmission in Nigeria is expected to establish an important block of protected populations, thus increasing the impact of herd immunity in the centre of the meningitis belt.

The program will target the at-risk population aged 1-29 years in 25 states and FCT in the Meningitis belt (81, 619,808 people). The campaign will be rolled out in three phases from 2011-2013, starting in the North in November 2011. This approach will protect the states with the highest case burden first and optimize herd immunity effects for the entire population, while minimizing the burden on the health system. The aim is to achieve 95% coverage in the target population in the meningitis belt of Nigeria by end of 2013.

Preparations will start immediately following confirmation of GAVI approval of support. Key components of the planning phase include establishing a national coordinating body and intersectoral subcommittees, conducting resource mobilization activities, developing training materials, logistics and data management tools, organizing state, LGA and ward level training and micro-planning, and conducting social mobilization activities.

In order to have sufficient cold storage for the Meningitis A vaccines (129, 021 liters capacity required in Phase 1), Nigeria will complete its planned cold chain expansion and rehabilitation at national and zonal levels. This effort is being funded by both the government and development partners, and with its completion Nigeria will have sufficient capacity to accommodate the campaign vaccines with little concern for their impact on the routine immunization system.

As part of the program, Nigeria aims to establish a pharmaco-vigilance system and to strengthen the surveillance infrastructure for cerebrospinal meningitis. In addition, the MenAfriVac program will be leveraged to strengthen critical components of the health system more broadly, including cold chain capacity and waste management.

Building on the experience with successful measles and polio campaigns, and in light of the acute community awareness of Meningitis, demand for Meningitis A vaccination is expected to be high. A post-implementation coverage survey will be conducted within four weeks of the conclusion of the campaign.

The estimated cost of the campaign in 2011-2013 is US\$ 101,321,236.00, including \$36, 706,008 for operational costs. The Government of Nigeria would welcome GAVI support for the campaign and is committed to raise the resources necessary to fund the remainder of the operational costs, amounting to US\$18,353,003.99. Overall the cost per person vaccinated in Nigeria will be 1.24USD.

2 Signatures of the Government and National Coordinating Bodies

Government and the Inter-Agency Coordinating Committee for Immunisation

The Government of Nigeria would like to expand the existing partnership with the GAVI Alliance for the improvement of the infants' routine immunisation programme of the country, and specifically hereby requests for GAVI support for Meningococcal A Conjugate Vaccine support.

The Government of Nigeria commits itself to developing national immunisation services on a sustainable basis in accordance with the cMYP and the MenA introduction plan presented with this document. The Government requests that the GAVI Alliance and its partners contribute financial and technical assistance to support immunisation programme as outlined in this application.

Table N° 6.1of page 19 of this application shows the amount of support in either supply or cash that is required from the GAVI Alliance. Table N° 6.2 of page 19 of this application shows the Government financial commitment for the operational costs of the campaigns.

Please note that this application will not be reviewed or approved by the Independent Review Committee without the signatures of both the Minister of Health and Finance or their delegated authority.

| Minister | of Health: | Minister | of Finance: |
|-----------|-----------------------|-----------|-----------------|
| Signature | e: | Signature | 9: |
| Name: | Prof Onyebuchi Chukwu | Name: | Olusegun Aganga |
| Date: | | Date: | |

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

We the members of the ICC/¹ met on the 25th day of February 2011 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: 2

| Name/Title | Agency/Organisation | Signature |
|-----------------------|---------------------|-----------|
| Prof Onyebuchi Chukwu | FMOH | |
| Alhaji Suleiman Bello | FMOH | |
| Dr Muhammad Ali Pate | NPHCDA | |
| Dr Paul Orhii | NAFDAC | |
| Dr Alex Gassasira | WHO | |
| Dr Suomi Sakai | UNICEF | |
| Jane Miller | DFID | |
| Dr Ray Kirkland | USAID | |
| Rot. Busuyi Onabolu | ROTARY | |

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

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

Name: Dr Muhammad Ali Pate Title: Executive Director/CEO

Tel No: +2347034156999 Address: National Primary Health Care

Development Agency

Plot 681/682 Port Harcourt Crescent

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Abuja

Fax No.: Email: Muhammad.pate@gmail.com

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/HSCC

Name of the ICC/HSCC: INTER - AGENCY COORDINATING COMMITTEE FOR IMMUNIZATION IN NIGERIA

Date of constitution of the current ICC/HSCC: 2000

Organisational structure (e.g., sub-committee, stand-alone): STAND ALONE WITH SUBCOMMITTEES (CORE GROUP AND ICC FINANCE) WITH 5 WORKING GROUPS THAT REPORT TO THE CORE GROUP) OPERATION, LOGISTICS, TRAINING, SOCIAL MOBILIZATION AND MONITORING & EVALUATION

| Frequency of meetings: | Initially Monthly b | ut changed to | quarterly plus | additional | meetings if |
|------------------------|---------------------|---------------|----------------|------------|-------------|
| necessary | | | | | |

Composition:

| Function | Title / Organisation | Name |
|-----------|--|--|
| Chair | Honourable Minister of Health | Prof Onyebuchi Chukwu |
| Secretary | NATIONAL PRIMARY HEALTH CARE DEVELOPMENT AGENCY(NPHCDA) | NATIONAL PRIMARY HEALTH CARE DEVELOPMENT AGENCY(NPHCDA) |
| Members | Hon Minister of State for Health Permanent Secretary FMOH Executive Director (NPHCDA) WR (WHO) Country Rep (UNICEF) Director Public Health (FMOH) Director Health Planning Research and Statistics (FMOH) Director General (NAFDAC) Charge D' Affairs of delegation of | Alh. Suleiman Bello Mr Linus Awute Dr Muhammad Ali Pate Dr Alex Gassasira (Ag.) Dr Suomi Sakai Dr M Kabir Dr Tolu Fakeye Dr Paul Orhii Mr Denis Thieulin |

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|----------|------|-----|-------|
| | | | 10112 |
| | | | |

- Health Adviser Dfid in Nigeria
- Mission Director (USAID)
- Chairman of Rotary Int. Nigeria
- Ambassador of Japan
- Country Director World Bank
- Secretary of Christian Health Association of Nigeria
- Senior Special Assistant to the President on MDG
- Country manager of MSF

- Dr Ebere Anyachukwu
- Dr Ray Kirkland
- Rot Busuyi Onabolu
- Amb. Toshitsugu Uesawa
- Mr Onno Ruhl
- Patrick Kwakfut
- Hajia Amina Alzubair
- William Hennequin

Major functions and responsibilities of the ICC/HSCC:

It provides forum for regular information sharing and networking amongst the major stakeholders so as to ensure synergy and complementarity of programme implementation.

Mobilization of resources for supplemental and Routine Immunization

Review and endorsement of action plans: 5 Year comprehensive Multi Year plan (cMYP) and Annual plans

Coordination of Partners efforts in support of Govt. activities

Review of progress reports on Immunization in the Country

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

- 1. Improved partnership coordination and information sharing
- 2. Joint budgeting and resource mobilization
- 3. Facilitating the establishment of functioning ICCs at lower levels (States and LGAs)

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 cMYP and the MenA introduction plan, and attach a complete copy (with an executive summary) as DOCUMENT NUMBER 3
- Please refer to Health Sector Strategy documents, budgetary documents, and other reports, surveys etc, as appropriate.

Table 3.1: Basic facts for the year 2011 (the most recent; specify dates of data provided)

| | Figure | Year | Source |
|----------------------------------|--------------------|------|-----------------------------------|
| | | | Projection from 2006 National |
| Total population | 163,884,360 | 2011 | Census |
| | | | 2008 Nigeria Demographic & Health |
| Infant mortality rate (per 1000) | 75/1000 Live birth | 2007 | Survey |
| | | | Projection from 2006 National |
| Surviving Infants* | 6,063,721 | 2011 | Census |

| GNI per capita (US\$) | 1,190 | 2009 | World Bank (Atlas Method) |
|---|-------|-------------|----------------------------------|
| Percentage of GDP allocated to Health | 8.5 | 2005 | National Health 2010 - 2015 |
| Percentage of Government expenditure on | | | |
| Health | 24 | 2003 - 2005 | NHA Estimation Final Report 2009 |

^{*} 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 Plan 2009 -2015

Is the cMYP (or updated Multi-Year Plan) aligned with this document (timing, content, etc). If not, please attach an introduction plan of the MenAfrivac for the upcoming mass campaign Yes

Please indicate the national planning budgeting cycle for health Annually January - December

Please indicate the national planning cycle for immunisation Annual Planning (January - December) from the cMYP

Please indicate if sex disaggregated data (SDD) is used in immunisation routine reporting systems No

Please indicate if gender aspects relating to introduction of this vaccine have been addressed in the introduction plan

No

Table 3.2: Current Vaccination Schedule: Traditional, New Vaccines and Vitamin A Supplement (refer to cMYP pages)

| | Ages of administration | | by an "x" if ven in: | |
|------------------------------------|------------------------------------|----------------|-----------------------------|-----------------------------------|
| Vaccine (do not use trade name) | (by routine immunisation services) | Entire country | Only part of the country | Comments |
| BCG | At Birth | X | | |
| DPT | At 6, 10 and 14 weeks | X | | |
| Polio | At Birth, 6, 10 and 14 weeks | X | | |
| Measles | At 9 months | X | | |
| Yellow Fever | At 9 months | X | | |
| Нер В | At Birth, 10 and 14 weeks | X | | With planned introduction of HiB. |

| | | | Vaccine, it will align with DPT schedule. |
|--------------|-------------------------|---|---|
| TT | Pregnancy and WCBA | X | |
| Vitamin A | Infants 6 months and 12 | X | |
| Vitaliili 71 | months | | |

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 burde | | | |
|---|-------------------------------------|------|-------------------------|-------|-----------------------------------|---------------------------|--------|--------|
| | Vaccine | | Vaccine Reported Survey | | Disease | Number of reported cases | | |
| | | 2008 | 2009 | 2006* | 2008** | | 2008 | 2009 |
| BCG | | 74.0 | 75 | 41 | 47.9 | Tuberculosis* | 32,944 | 46,889 |
| DTP | DTP1 | 83.0 | 91 | | 52.0 | Diphtheria | 0 | 0 |
| | DTP3 | 71.0 | 79 | 36 | 35.4 | Pertussis | 13,260 | 11,281 |
| Polio 3 | | 61.0 | 70 | 37 | 38.7 | Polio | 803 | 388 |
| Measles (first | dose) | 86.0 | 90 | 33 | 41.4 | Measles | 9,960 | 1272 |
| TT2+ (Pregna | nt women) | 62.0 | 47 | 7.0 | | NN Tetanus | 721 | 90 |
| Hib3 | | | | | | Hib ** | | |
| Yellow Fever | | 64.0 | 69 | 27 | | Yellow fever | 0 | 0 |
| HepB3 | | 62.0 | 72 | 30 | | hepB sero- prevalence* | | |
| Vit A | Mothers (<6 weeks post-delivery) | | | | | | | |
| supplement | Infants (>6 months) | | | | | | | |

^{*} If available

2006* National Immunization Coverage Survey (NICS) 2008** Nigeria Demographic and Health Survey

Table 3.4: Trends of coverage during the last mass campaign

| Vaccine | Reported | Survey | wastage rate |
|---|-------------|--------|--------------|
| | 20 | 20 | 20 |
| Polio (November 2010 National Immunization Plus days) | 53,000,000* | | |
| Measles (2008 Integrated campaign) | 112% | | |
| TT2+ (Pregnant women) Three States IN 2009 | 88% | | |

^{*}In polio campaigns, the absolute number of children immunized is used

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:

^{**} Note: JRF asks for Hib meningitis from 2010 data collection onwards

Table 3.5: Baseline and annual targets

Please refer to the cMYP and the MenA introduction plan pages containing baseline and annual targets to complete the mandatory excel sheet (Annex 1).

Table 3.6: Summary of current and future immunisation budget (refer to cMYP pages) Table 3.6 is an updated table in the cMYP, as introduction of pentavalent was not done in 2010

| | Estimated costs per annum in US\$ (in thousands) | | | | | | |
|--|--|-------------|-------------|-------------|----------------|----------------|--|
| Cost category | Base year | Year 1 2011 | Year 2 2012 | Year 3 2013 | Year 4 2014 | Year 5 2015 | |
| Routine Recurrent Cost | 2008 | | | | | | |
| Vaccines (routine vaccines only) | 22,300,000 | 88,628,959 | 220,754,182 | 304,443,486 | | | |
| a) Traditional vaccines | 17,000,000 | 10,669,719 | 12,759,541 | 14,904,651 | | | |
| b) New and underused vaccines | 5,300,000 | 77,959,240 | 207,994,641 | 289,538,835 | | | |
| Injection supplies | 7,014,302 | 6,167,904 | 8,950,088 | 11,034,640 | | | |
| Personnel | 55,625,053 | 66,767,874 | 68,103,232 | 69,465,296 | | | |
| a) Salaries of full-time NIP health workers (immunisation specific) | 8,763,514 | 9,318,971 | 9,505,350 | 9,695,457 | | | |
| b) Per-diems for outreach vaccinators / mobile teams | 46,861,538 | 57,448,903 | 58,597,881 | 59,769,839 | | | |
| Transportation | 342,717 | 511,333 | 554,351 | 264,673 | | | |
| Maintenance and overheads | 9,371,597 | 14,269,544 | 15,428,191 | 15,782,420 | | | |
| Training | 1,675,310 | 0 | 566,240 | 0 | | | |
| Social mobilisation and IEC | 6,348,712 | 6,424,173 | 6,060,926 | 6,803,940 | | | |
| Disease surveillance | 1,477,464 | 5,286,955 | 5,715,870 | 6,574,167 | | | |
| Program management | 613,599 | 838,304 | 855,070 | 872,172 | | | |
| Other | 100,000 | 106,121 | 108,243 | 110,408 | | | |
| Subtotal Recurrent Costs | 104,868,754 | 189,001,168 | 327,096,393 | 415,351,202 | | | |
| Routine Capital Costs | | | | | | | |
| Vehicles | 242,400 | 1,529,201 | 867,461 | 784,670 | | | |
| Cold chain equipment | 4,227,713 | 5,848,635 | 6,266,423 | 5,994,193 | | | |
| Other capital equipment | 40,340 | 2,987,724 | 1,084,759 | 835,568 | | | |
| Subtotal Capital Costs | 4,510,453 | 10,365,560 | 8,218,643 | 7,614,432 | | | |
| Campaigns | | | | | | | |
| Polio | 102,600,970 | 90,430,207 | 91,630,207 | 92,890,207 | | | |
| Measles | 29,468,260 | 32,562,702 | 0 | 0 | | | |
| Yellow Fever | 0 | 16,933,461 | 16,933,461 | 16,933,461 | | | |
| MNT campaigns | 0 | 3,558,784 | 4,789,527 | 0 | | | |
| Other campaigns | 0 | 0 | 0 | 0 | | | |

| Subtotal Campaign Costs | 132,069,230 | 143,485,154 | 113,353,195 | 126,757,129 | |
|---|-------------|-------------|-------------|-------------|--|
| Shared Health Systems Costs | | | | | |
| Shared personnel costs | 24,067,759 | 34,496,106 | 35,186,028 | 35,889,748 | |
| Shared transportation costs | 27,685 | 29,379 | 29,967 | 30,566 | |
| Construction of new buildings | 5,946,060 | 32,088,808 | | | |
| Subtotal Shared Health Systems Costs | 30,041,504 | 66,614,292 | 35,215,995 | 35,920,314 | |
| GRAND TOTAL | 271,489,941 | 409,466,174 | 483,884,226 | 585,643,077 | |

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 (refer to the the cMYP and/or the MenA introduction plan)

| | | Estim | Estimated financing per annum in US\$ (in millions) | | | | | | |
|--|--|----------------|---|----------------|----------------|-------------------|-------------------|--|--|
| Cost category | Funding source | Base year 2008 | Year 1 2011 | Year 2 2012 | Year 3 2013 | Year 4 2014 | Year 5 2015 | | |
| Routine Recurrent (| Cost | | | | | | | | |
| Vaccines (routine vaccines only) | 1.GOVERNMENT | 22,300,000 | 88,628,959 | 220,754,182 | 304,443,486 | | | | |
| a) Traditional vaccines | 2.GOVT | 17,000,000 | 10,669,719 | 12,759,541 | 14,904,651 | | | | |
| b) New and underused vaccines | 3.GOVT & GAVI YF | 5,300,000 | 77,959,240 | 207,994,641 | 289,538,835 | | | | |
| Injection supplies | 4.GOVT & GAVI | 7,014,302 | 6,167,904 | 8,950,088 | 11,034,640 | | | | |
| Personnel | 5.GOVT | 55,625,053 | 66,767,874 | 68,103,232 | 69,465,296 | | | | |
| a) Salaries of full-time NIP health workers (immunisation specific) | 6.GOVT | 8,763,514 | 9,318,971 | 9,505,350 | 9,695,457 | | | | |
| b) Per-diems for outreach vaccinators / mobile teams | 7.GOVT | 46,861,538 | 57,448,903 | 58,597,881 | 59,769,839 | | | | |
| Transportation | 8.GOVT | 342,717 | 511,333 | 554,351 | 264,673 | | | | |
| Maintenance and overheads | 9. GOVT | 9,371,597 | 14,269,544 | 15,428,191 | 15,782,420 | | | | |
| Training | 10. GOVT | 1,675,310 | 0 | 566,240 | 0 | | | | |
| Social mobilisation and IEC | 11.GOVT & PARTNERS (WHO, UNICEF) | 6,348,712 | 6,424,173 | 6,060,926 | 6,803,940 | | | | |
| Disease surveillance | 12. GOVT & WHO | 1,477,464 | 5,286,955 | 5,715,870 | 6,574,167 | | | | |
| Program management | 13.GOVT | 613,599 | 838,304 | 855,070 | 872,172 | | | | |
| Other | GOVT | 100,000 | 106,121 | 108,243 | 110,408 | | | | |
| Subtotal Recurrer | nt Costs | 104,868,754 | 189,001,168 | 327,096,393 | 415,351,202 | | | | |

| Routine Capital Cost | | | | | | |
|-------------------------------|--|-------------|-------------|-------------|-------------|--|
| 1.Vehicles | GOVT | 242,400 | 1,529,201 | 867,461 | 784,670 | |
| 2.Cold chain equipment | GOVT & PARTNERS (UNICEF, EC Delegation) | 4,227,713 | 5,848,635 | 6,266,423 | 5,994,193 | |
| 3.Other capital equipment | GOVT & PARTNERS (WHO, UNICEF, JICA) | 40,340 | 2,987,724 | 1,084,759 | 835,568 | |
| Subtotal Routine | Capital Cost | 4,510,453 | 10,365,560 | 8,218,643 | 7,614,432 | |
| Campaigns | | | | | | |
| Polio | 1.GOVT, PARTNERS (WORLD BANK, WHO, UNICEF, ROTARY) | 102,600,970 | 90,430,207 | 91,630,207 | 92,890,207 | |
| Measles | 2.GOVT, PARTNERS (WHO, UNICEF, LION CLUB) | 29,468,260 | 32,562,702 | 0 | 0 | |
| Yellow Fever | 3. GOVT, PARTNERS (WHO, UNICEF) | 0 | 16,933,461 | 16,933,461 | 16,933,461 | |
| MNT campaigns | 4. GOVT, PARTNERS (WHO, UNICEF, ROTARY) | 0 | 3,558,784 | 4,789,527 | 0 | |
| Other campaigns | 5. GOVT, PARTNERS (WHO, UNICEF) | 0 | 0 | 0 | 0 | |
| Subtotal Campaign | Cost | 132,069,230 | 143,485,154 | 113,353,195 | 126,757,129 | |
| Shared Health S | Systems Costs | | | | | |
| Shared personnel costs | 4. GOVT, PARTNERS (WHO, UNICEF,) | 24,067,759 | 34,496,106 | 35,186,028 | 35,889,748 | |
| Shared transportation costs | 4. GOVT, PARTNERS (WHO, UNICEF,) | 27,685 | 29,379 | 29,967 | 30,566 | |
| Construction of new buildings | 4. GOVT, PARTNERS | 5,946,060 | 32,088,808 | | | |
| Subtotal Shared Costs | Health Systems | 30,041,504 | 66,614,292 | 35,215,995 | 35,920,314 | |
| GRAND TOTAL | | 271,489,941 | 409,466,174 | 483,884,226 | 585,643,077 | |

Request for Meningococcal A conjugate Vaccine Support

Please give a summary of the cMYP and/or the MenA introduction plan sections that refer to the introduction of Meningococcal A vaccines. Outline the key points that informed the decisionmaking process (data considered etc):

The last major meningitis outbreak in Nigeria was in 1996, when over 100 000 suspected cases were reported.

In 2008, 6835 cases including 492 deaths (7.2% case fatality rate) were reported. By the end of the 2008 meningitis season, 27 Local Government Areas (LGAs) had crossed the alert threshold and 51 the epidemic threshold, primarily among 4 states. Most cases in 2008 were reported late in the season and due to the late detection and some surveillance gaps, only a small, targeted epidemic response was launched. Bacteriology information was inadequate.

The 2009 epidemic was devastating with over 55,720 cases and 2,257 deaths. During this period, a total of 220 LGAs in 16 States were in either alert or epidemic threshold. Bacteriology information indicated a preponderance of Men A (with 375 positives) followed by W135 (20 cases).

Preventive mass campaigns with Men A conjugate vaccine is believed to halt similar large-scale epidemics due to Men A sero group and eventually eliminate it from the country.

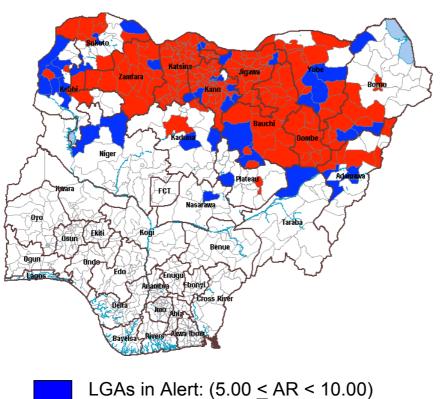


Figure 1 Summary of the 2009 CSM epidemic, Nigeria

LGAs in Epidemics: (AR > 10.00)

Nigeria has an official population of 163 million. The country shares international border with 4 countries

namely Republic of Niger in the NW, Chad in the NE, Cameroon in the SE and Republic of Niger Benin in the SW.

The meningitis belt, in Nigeria, sweeps through northern Nigeria with expansion downwards towards the southern part of the country. There are 26 states currently lying in the meningitis belt with an estimated population of 80 million.

Due to its size among other issues a phased introduction over 3 years (2011- 2013) has been planned to ensure better implementation and coordination of the campaigns. To this end, it is planned that campaign will first be introduced in Northern Nigeria more specifically in the states bordering the Republic of Niger (where vaccine would have already been introduced) in order to optimize the herd immunity effect.

For the 1st phase of the campaigns, ten states that share common border with the Republic of Niger and those that had high meningitis burden in the 2009 epidemic are selected (Kebbi, Sokoto, Zamfara, Jigawa, Katsina, Kano, Yobe, Bauchi, Gombe and Borno States) are proposed. Kano is included in phase one considering its population size and its active population movement with Niger Republic. Two additional States (Bauchi and Gombe) were severely hit by the 2009 meningitis epidemic. Most of these States had high case burden during the recent meningitis epidemics and have a target population of 35.4 million (figure 1).

The second phase, in 2012, will target other nine high and medium risk states located south of the States in phase one. These nine states have target population of 23.5 million.

The third phase will include seven endemic states with a target population of 20.5 million.

Figure 2: Rollout Plans for Phased introduction of Men A vaccine in 26 States, Nigeria



Experiences from the countries that implemented these campaigns have shown that preparatory activities need to begin 9-12 months before the campaigns. Accordingly, planning activities, meetings and discussions with the State Ministry of Health of concerned States have commenced in Nigeria. This will enable the country to conduct a high quality campaign by the end of the year.

Please summarise (1) the waste management plan and (2) 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 indicate if the supplies for the campaign will have any impact in the shipment plans for your routine vaccines and how it will be handle:

(1) Waste management

Nigeria has a national health care waste management policy (NHCWM) that has been developed and approved by the National Assembly though the policy is still awaiting implementation by the government and stakeholders.

The 'burn and bury' method of waste disposal is routinely used for immunization waste disposal. Previous efforts at entrenching global standards for waste management have not borne fruit. The Men A vaccination campaign will provide a platform for the entrenchment of appropriate waste management practices in the system. Mapping of existing waste management facilities will be conducted. In addition, each senatorial zone in the states conducting the Men A campaign will be equipped with at least one standard WDU to cater for LGAs within the senatorial zone. The states will further advocate to the LGAs to provide one WDU in each LGA headquarter.

(2) Cold Chain Readiness

The vaccine cold chain in Nigeria is comprised of one National Strategic Cold Store (NSCS) at the National level in Abuja, 6 zonal cold stores, 37 state cold stores and 774 LGA cold stores. In addition, some Health Facilities have cold storage capacity for vaccine storage in line with the ward health system policy.

The current cold storage capacities at the NSCS are 28,571 and 9,524 liters positive and negative storage respectively. The combined positive storage capacity at the zonal stores is 86,905 liters. Thus together, the total positive storage capacity at the NSCS and zonal stores is 115,476 liters. This storage capacity is sufficient to accommodate the storage needs of the current vaccines in Nigeria's routine immunization schedule, as these vaccines require 89,268 liters and 8,508 liters respectively of positive and negative cold storage capacity.

The current cold chain capacity at national and zonal levels is not presently sufficient, however, to accommodate the storage needs of both Nigeria's routine vaccines as well as those required for the Men A campaign, for which the first phase will require an estimated 129,021liters. Accommodating the Men A vaccines will require the on-going cold chain expansion and rehabilitation which is being supported by both the government and partners (\$6.73m USD total). The planned expansion will add 89,286 and 53,571 liters of positive and negative cold storage capacity respectively at the zonal and national levels to provide a combined positive storage capacity of 204,762 liters. This capacity will be sufficient to store routine vaccines and conduct the MenA campaign.

The current capacity and expansion plans are summarized in the table below.

| | Positive storage capacity (L) |
|--|-------------------------------|
| Current capacity at NCSC | 28571 |
| Current capacity at zones | 86,905 |
| Planned expansion | 89,286 |
| Total capacity available after expansion | 204,672 |
| | |

| Capacity required for RI | 89,268 |
|-----------------------------|---------|
| Capacity required for Men A | 92,040 |
| (phase 1) | |
| Total capacity required | 181,308 |

At state and LGA levels, a recent inventory conducted by the government (June 2010) in the phase 1 states indicates that there is largely sufficient capacity to store the vaccines for the Men A campaign. In states where there is not sufficient storage capacity, states with adequate storage capacity will serve as temporary storage sites. In addition, the zonal cold stores can be used as depot storage sites for buffer stocks, and these zones will help accommodate the MenAfriVac for states within its zone. Further, as part of preparing for the campaign, another extensive inventory assessment of the existing cold chain equipment will be done to determine the capacity of the states and LGAs to implement the campaign. The inventory assessment will involve visits to LGA and State cold chain stores to identify gaps in cold chain capacity, and where possible, rapid procurement of equipment will be made to address such gaps.

It is expected that, at many levels, the delivery schedules for routine vaccines will need to be adjusted to accommodate the storage and delivery of the Men A vaccine. Logistics micro-planning will be conducted in each state and LGA well in advance of the campaign, such that there is minimal impact on the supply of routine vaccines. The government does not anticipate any challenges for the RI programme due to the Men A campaign, particularly as the campaign will be condensed over a brief 10-day period.

Table 4.1: Capacity and cost (for positive storage)

| | | Formula | Year 1 2011 | Year 2 2012 | Year 3 2013 | Year 4 2014 | Year 5 2015 |
|---|---|--|----------------|----------------|----------------|----------------|----------------|
| A | Annual <i>positive</i> volume requirement, including new vaccine (specify:) (litres or m3) ² | Sum-product of total vaccine doses multiplied by unit packed volume of the vaccine | 372124 | 634033 | 736517 | 779440 | 804386 |
| В | Annual <i>positive</i> capacity, including new vaccine (specify:) (litres or m3) | # | 28571 | 57142 | 57142 | 57142 | 57142 |
| С | Estimated minimum number of shipments per year required for the actual cold chain capacity | A/B | 13 | 11 | 13 | 14 | 15 |
| 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) | 64814 | 83,387 | 103,466 | 113,895 | 143955 |
| F | Estimated cost for expansion | US \$ | 707,350 | 45,700 | 22,850 | 22,850 | 22,850 |

This capacity requirement is based on the phased introduction plan for pentavalent as opposed to the full implementation that was in the cMYP forcasting tool.

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).

Clinical studies of MenAfriVac in under ones are ongoing and an infant indication is expected by January 2014. Please briefly describe when your country plans to move towards introducing the Meningococcal A conjugate vaccine into the routine schedule, how the country will meet the future co-financing payments for routine introduction of Meningococcal A conjugate vaccine, and any other issues regarding the introduction into the routine schedule that you have considered (refer to the cMYP and/or the MenA introduction plan):

In the 2009 – 2014 cMYP of the country, Meningococcal conjugate A vaccine is not listed as part of the routine immunization schedule antigen, however the country will be willing to introduce when the benefits have been established after all the ongoing clinical studies. Nigeria procures her routine vaccines from government funds and the same process of procurement will be applied to meningococcal A conjugate vaccine when the decision to include it as a routine vaccine is taken.

Table 4.2: Assessment of disease burden related to Meningococcus (if available):

| Disease | Title of the assessment | Date | Results |
|-----------------------------|--|----------|--|
| Cerebrospinal meningitis | CSM surveillance in Nigeria | Dec 2008 | Cases: 6835 Deaths: 492 CFR: 7.2 Cumulative A/Rate: 6.7 No bacteriology data |
| Cerebrospinal meningitis | CSM surveillance in Nigeria | Dec 2009 | Cases: 56135 Deaths: 2489 CFR: 4.4 Cumulative A/Rate: 52.6 |
| Cerebrospinal meningitis | Evaluation report of the preparedness and response to the 2009 CSM epidemic in Nigeria | 2010 | Bacteriology information indicated a preponderance of Men A (with 375 positives) followed by W135 (20 cases) |
| Cerebrospinal meningitis | CSM surveillance in Nigeria | Dec 2010 | Cases: 4983 Deaths: 337 CFR: 6.8 Cumulative A/Rate: 4.7 NmA: 43 W135: 58 |

If new or under-used vaccines have already been introduced in your country or you have conducted campaigns, please give details of the lessons learnt from storage capacity, social mobilisation, staff training, cold chain, logistics, dropout rate, wastage rate etc., and suggest solutions to address them:

| Lessons Learned | Solutions / Action Points |
|---|---|
| When Hep B was introduced in the schedule in 2004, the health workers were not knowledgeable enough on the storage and handling of the vaccines. | There was a lot of capacity building of Health Workers to address these gaps. |
| There was also no clear-cut policy on the target group to be vaccinated with the Hep B at time of introduction. | This was addressed with capacity building of Health workers. |
| No adequate information about the introduction of the new vaccine into the schedule | Intensive Social Mobilization and Health Education prior to and during the introduction of the new vaccine |
| Observations of significant quantities of HepB vaccine that appeared to have been wasted or unused were noted in several states one year after introduction | Re-training of health workers on cold chain logistics and temperature monitoring. |
| Poor HepB introduction workplanning and coordination; little documentation on pre-introduction planning, such as cold chain preparation and expansion, training, social mobilization, and M&E | The ICC using the various working groups developed work-plan for upcoming introductions which lay out clear activities, parties responsible and timelines for introduction preparation |
| During the previous measles campaign, the storage capacity at the National Strategic Cold Store was inadequate to receive all the supplies at once | The vaccines on arrival and clearance at the National Strategic Cold store were moved immediately to the closest National Zonal cold stores within 2 hours and distribution to States could be carried out from the zonal stores. |

5. Procurement and Management of the MenAfrivac

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

The government of Nigeria has an existing MOU with UNICEF for the procurement of her vaccines and injection safety materials both for routine immunization and campaigns. This MOU will be extended for the procurement of the Meningococcal A conjugate vaccine for this campaign.

The consignee NPHCDA does shipment and clearing of supplies once the goods are shipped to Nigeria. NPHCDA gets custom waivers annually from the Federal government for vaccines and injectables and it is renewable on a yearly basis.

b) Please indicate when you are planning to conduct the campaign (month and year) and how the campaign is going to be rolled out (e.g. in different phases or one time).

The campaign will be rolled out in three phases from November 2011 to 2013.

The first phase, November 2011, will include 10 very high-risk states (those along Niger republic) and others that were severely hit during the 2009 epidemic. The target population is 35.4 million.

The second phase will be in 2012 targeting another 9 states situated South of those indicated in phase one. The target population is 23.5 million.

The third phase in 2013 will include seven states with target population of 20.6 million.

| | Phase 1:2011 | | | | Phase 2: 2012 | | | Phase 3: 2013 | | |
|-----|--------------|------------|------------|----------|---------------|------------|-------------|---------------|------------|--|
| | | Total | Target | | Total | Target | | Total | Target | |
| No. | STATE | Population | Population | STATE | Population | Population | STATE | Population | Population | |
| 1 | Bauchi | 5,345,642 | 3,869,175 | Adamawa | 3,551,898 | 2,558,432 | Anambra | 4,670,462 | 3,360,864 | |
| 2 | Borno | 4,745,206 | 3,434,580 | Benue | 4,748,796 | 3,423,882 | Cross River | 3,238,948 | 2,333,014 | |
| 3 | Gombe | 2,669,949 | 1,928,771 | FCT | 2,005,484 | 1,534,395 | Ebonyi | 2,427,349 | 1,746,721 | |
| 4 | Jigawa | 4,875,463 | 3,511,796 | Kaduna | 6,827,969 | 4,922,966 | Enugu | 3,666,118 | 2,643,271 | |
| 5 | Kano | 10,685,001 | 7,726,324 | Kwara | 2,668,682 | 1,924,119 | Imo | 4,463,262 | 3,224,260 | |
| 6 | Katsina | 6,516,598 | 4,700,630 | Nasarawa | 2,097,132 | 1,512,032 | kogi | 3,689,966 | 2,660,465 | |
| 7 | Kebbi | 3,659,281 | 2,640,903 | Niger | 4,515,508 | 3,268,325 | Оуо | 6,391,715 | 4,626,323 | |
| 8 | sokoto | 4,161,005 | 3,000,085 | Plateau | 3,536,169 | 2,542,152 | | | | |
| 9 | Yobe | 2,664,079 | 1,930,125 | Taraba | 2,556,750 | 1,841,627 | | | | |
| 10 | Zamfara | 3,697,565 | 2,671,121 | | | | | | | |
| Т | otal | 49,019,789 | 35,413,510 | | 32,508,388 | 23,527,930 | | 28,547,820 | 20,594,918 | |

c) Please outline how coverage of the new vaccine will be monitored and reported (refer to the cMYP and/or the MenA introduction plan)

The coverage of the meningococcal A conjugate vaccine will be monitored using administrative data during the campaign. Coverage will also be monitored using independent reports from independent monitors engaged during the campaign. At the end of the campaign a post campaign evaluation survey will be carried out.

In addition, a specific effort will be put on pharmaco-vigilance activities in order to monitor AEFI in Nigeria following the introduction of the vaccine. AEFI case investigation forms would be completed for every case and treatment kits stationed at all vaccination sites. Campaign evaluation and pharmaco-vigilance activities will be boosted by issuance of record cards to vaccinees.

Surveillance will be intensified in sentinel referral / teaching hospitals in state capitals with case based and bacteriology information. Two clinicians and two laboratory focal points will be designated in the sentinel sites. These clinician and lab personnel will be trained on sample collection and processing procedures. One clinician will be designated to coordinate the overall CSM surveillance activities, which includes reporting to the state level of data on cases and laboratory information on weekly bases. The state epidemiologist will make weekly visits to monitor timeliness and completeness of reporting.

6. Grant Support for Operational Costs of the Campaigns

Table 6.1: calculation of grant to support the operational costs of the campaigns

| Year of New Vaccine introduction | Target 1-29 years old (from table 3.4) | Share per birth in US\$ | Total in US\$ |
|----------------------------------|--|-------------------------|---------------|
| 2011 | 35.4 million | \$ 0.30 | US\$14.33m |
| 2012 | 24.3 million | \$ 0.30 | US\$10.10m |
| 2013 | 21.8 million | \$ 0.30 | US\$ |

GAVI Alliance budgeted operational support was put at 0.3USD per person vaccinated, however the operational cost for the campaign is less as attached in the detailed cost in the excel spreadsheet. The Country has decided to fund 50% of the operational cost while GAVI funds 50%, which is less than 0.3USD per target person.

Please indicate in the tables below how the support Grant will be used to support the operational costs of the campaign and other critical pre-introduction activities. GAVI's support will not be enough to cover the full needs so please indicate in the table below how much and who will be complementing the funds needed (refer to the cMYP and the MenA introduction plan).

Table 6.2: Cost (and finance) of the Campaign (US\$)

| Cost Category | Full needs for the campaign | Funded with GAVI grant | Funded with other sources ³ | |
|---------------------------------------|-----------------------------|------------------------|--|--|
| | US\$ | US\$ | US\$ | |
| Training | 648,405 | 324,202.5 | 324,202.5 | |
| Social Mobilisation, IEC and Advocacy | 3,188,677 | 1,594,338.4 | 1,594,338.4 | |
| Cold Chain Equipment & Maintenance | 3,423,138 | 1,711,569.04 | 1,711,569.04 | |
| Vehicles and Transportation | 3,454,593 | 1,727,296.6 | 1,727,296.6 | |
| Human Resources (per diem) | 10,781,006 | 5,390,503.2 | 5,390,503.2 | |
| Surveillance and Monitoring | 10,601,291 | 5,300,645.28 | 5,300,645.28 | |
| Waste management | 3,919,376 | 1,959,687.91 | 1,959,687.91 | |
| Planning | 689,522 | 344,761.05 | 344,761.05 | |
| TOTAL | 36,706,008 | 18,353,003.99 | 18,353,003.99 | |

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

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³ Please specify between () the source

Please briefly describe who will be funding the operational needs that GAVI will not fund. If the government is the source of funding please confirm if it is already budgeted in your health budget. If you are looking for other sources of funding please clarify them and provide confirmation of their commitment:

As at March 4th 2011 (application deadline date), the 2011 budget of the government of Nigeria is yet to be finalized. In the event of budget not capturing provision for the operational cost of the campaign, the government of Nigeria will use the supplementary budget instrument to concretize government's commitment in this effort. In subsequent years, government is committed to ensuring adequate provision is made in capturing the operational cost as it is being done with other supplemental immunization activities (Polio eradication, Measles and MNTE). A memorandum of understanding will be signed with the implementing States and local governments to that effect. Creative advocacy will be employed.

7 Additional comments and recommendations from the National Coordinating Body (ICC/HSCC)

The Nigeria Inter Agency Coordinating Committee for immunization appreciates the support GAVI has been rendering to Nigeria. The ICC also understands the benefit the GAVI support for meningococcal conjugate A vaccine campaign will have in reducing the mortality and morbidity associated with cerebrospinal meningitis in the country. To this end, members of the ICC endorses and support the plan to introduce the meningococcal A conjugate vaccine campaign in the country for a three year period starting from the last quarter of 2011.

8 Documents required for this support

| Document | DOCUMENT NUMBER | Duration * |
|---|--------------------|------------|
| Comprehensive Multi-Year Plan (cMYP) (Already submitted with 2009 APR) | 3 | 2009 -2014 |
| Plan for introduction of the MenAfriVac (if not already included in the cMYP) | 4 | |
| Endorsed minutes of the National Coordinating Body meeting where the GAVI proposal was endorsed | 1 | |
| Endorsed minutes of the ICC/HSCC meeting where the GAVI proposal was discussed | | |
| Minutes of the three most recent ICC/HSCC meetings | | |
| 2.1 Feb 25 th 2011 (Meeting where proposal was discussed and endorsed) | | |
| | | |

2.2 June 2010

2.3 October 2009 (Already submitted with 2009 APR)

| ICC/HSCC workplan for the forthcoming 12 months | |
|---|-------|
| Vaccine Request Excel Sheet | 4 |
| Detailed costing sheet | 5 |
| Minutes of Inauguration of National organizing committee on CSM control | 6 |
| Minutes of Technical and Stakeholders meeting on MenAfriVac | 7 |
| Report of sensitization meeting with Honourable Commissioners of Health and State PHC Directors o | f the |
| phase one States on MenAfrivac introduction | 8 |

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



Banking Form

SECTION 1 (To be completed by payee)

It cannot be stressed enough that without a banking form that contains complete, accurate banking details (IBAN, SWIFT code, corresponding US bank and account details) it is impossible to transfer funds and this may cause many unnecessary delays.

| GAVI Alliance | | Banking Form | | |
|--|------------------------------|---------------------|--|--|
| SECTION 1 (To b | a countried by naves | | | |
| SECTION 1 (10 b) | e completed by payee) | | | |
| In accordance with the decision on financial support made by the GAVI Alliance, 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.: | | | |
| Currency of the | | | | |
| bank account: | | | | |
| For credit to: | | | | |
| Bank account's title | | | | |
| Bank account | | | | |
| No.: | | | | |
| At: | | | | |
| Bank's name | | | | |
| | | | | |
| Is the bank account program? | exclusively to be used by t | this YES () NO () | | |
| By whom is the acc | count audited? | | | |
| Signature of Govern | nment's authorising official | 1. | | |

| Name: | Seal: |
|------------|-------|
| Title: | |
| | |
| Signature: | |
| Date: | |
| | |

SECTION 2 (To be completed by the Bank)

| FINANCIAL INSTITUTION | CORRESPONDENT BANK | |
|--|--------------------------------------|--|
| | (In the United States) | |
| Bank Name: | | |
| Branch | | |
| Name: Address: | | |
| Auui css. | | |
| | | |
| City – | | |
| Country: | | |
| Swift code: | | |
| Sort code: | | |
| ABA No.: | | |
| Telephone | | |
| No. | | |
| Fax No.: | | |
| | | |
| I certify that the account No | | |
| The account is to be signed jointly by at least (number of signatories) of the following authorised signatories: | Name of bank's authorising official: | |
| 1 | Signature: | |
| Name: | Signature: | |
| | | |
| Title: | Date: | |
| | Cools | |
| Name: | Seal: | |
| manic. | | |
| Title: | | |
| | | |
| 3 | | |
| Name: | | |
| Title: | | |
| | | |
| 4 | | |
| Name: | | |
| T:41 | | |
| Title: | | |

ANNEX 2: GAVI Alliance Terms and Conditions

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION

The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARANCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.