GUIDELINES FOR APPLICATIONS

New and Underused Vaccines Support

2012

Application Deadline:

31 August 2012

Document updated June 2012

Please note that this is an updated version of the same Guidelines for Applications document that was originally released in early April 2012.

Based on proposed policy changes that were reviewed and approved by the GAVI Board at its meeting in June 2012, content on the following has been updated:
Vaccine introduction grant and support for operational campaigns policy

As a result, changes to content herein is highlighted in yellow on pages: 12, 13, 15, 18, 19, 22

Table of Contents

Acronyms and Abbreviations 3
1. Overview of support 4
1.1 Introduction 4
1.2 Eligibility for support 4
1.3 The application and review process in 2012 5
1.4 Accessing and completing the online application form 5
1.5 Checklist of mandatory documents 7
1.6 Application assessment and approval 7
2. Application requirements 9
2.1 Overall assessment criteria 9
2.2 Vaccine management 10
2.3 Monitoring and reporting 11
2.4 Financial requirements 13
2.5 Co-financing requirements 14
3. Vaccine introduction 15
3.1 The vaccine introduction grant 15
3.2 Readiness for introduction 16
3.3 Vaccine preferences and timing of supply availability 16
4. New vaccines support 18
4.1 Vaccine specific considerations 18

Annex A: Eligible countries and co-financing groupings 24
1. Countries eligible for GAVI new vaccines support in 2012. 24
2. Countries eligible for Meningococcal preventive campaigns 24
3. Co-financing groupings in 2012 25
Annex B: GAVI Alliance terms and conditions of support 26

Do you have any questions or comments about these guidelines?
Please contact proposals@gavialliance.org and we will direct your email to a colleague who will respond.
Any feedback is most welcome and will be used to help inform future GAVI communication planning.

Acronyms and Abbreviations

AD	Auto-disable (syringes)
AMC	Advance Market Commitment
APR	Annual progress report
cMYP	Comprehensive multi-year plan for immunisation
CRS	Congenital Rubella Syndrome
CSO	Civil society organisation
DTP3	Diphtheria-Tetanus-Pertussis, 3rd dose
DQA	Immunisation data quality audit
EPI	Expanded programme on immunisation
EVM	Effective Vaccine Management, an assessment tool
GDP	Gross domestic product
GNI	Gross national income
HSCC	Health Sector Coordination Committee
Hep B	Hepatitis B vaccine
Hib	*Haemophilus influenzae* type b
HPV	Human papillomavirus
ICC	Inter-Agency Co-ordination Committee for Immunisation
ICG	International Coordinating Group
IRC	Independent Review Committee
JRF	WHO / UNICEF Joint Reporting Form on Vaccine Preventable Diseases
LDC	UN Least Developed Country
Men A	Meningococcal A conjugate vaccine
MCV	Measles containing vaccine
MDG	Millennium development goals
MoF	Ministry of Finance
MoH	Ministry of Health
MMR	Measles, mumps, and rubella
MR	Measles and rubella (combined vaccine)
MSD	Measles second dose
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
NVS	New and underused vaccine support
PCV	Pneumococcal conjugate vaccine
Phase 1	GAVI Alliance Phase 1 Support (2000-2005)
Phase 2	GAVI Alliance Phase 2 Support (2006-2010)
RCV	Rubella-containing vaccine
RVV	Rotavirus vaccine
SAGE	WHO Strategic Advisory Group of Experts
SIA	Supplementary Immunization Activities
TAG	Technical Advisory Group
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WAP	Weighted average price
WCBA	Women of Childbearing Age
WHO	World Health Organization

1. Overview of support

1.1 Introduction

This document provides information on the **New and Underused Vaccines Support (NVS)** window available from the GAVI Alliance for the introduction of new and under-used vaccines. It provides information on the eligibility criteria, requirements, and application process to assist countries to submit proposals for the **2012 application round**.

New Vaccines Support
This type of support is provided to sustain the accelerated introduction of life-saving new and under-utilised vaccines. Countries can apply for the vaccines listed below:

- Human Papillomavirus[1] (HPV)
- Measles Rubella (MR)
- Measles Second Dose (MSD)
- Meningococcal A conjugate (Men A)
- Pentavalent (DTP-HepB-Hib)
- Pneumococcal
- Rotavirus
- Yellow fever

Focus on equity and gender
To attain MDGs 3, 4 and 5 there is a need to address social inequalities and gender and their impact on access to and use of essential health services, including immunisation and child health services. An effective and efficient introduction of new vaccines and expansion of underused vaccines will require an analysis of socio-economic and gender barriers to access and delivery. Through its Gender Policy, the GAVI Alliance is committed to addressing these barriers in order to increase vaccination coverage.

The GAVI Gender Policy focuses on:

- Generating, reporting and analysing new evidence
- Ensuring gender sensitive policy and funding support
- Advocating for gender equality as a means to improve coverage and access to services
- Introducing gender sensitive approaches in GAVI Alliance structures. This includes disaggregating data, including information on geographic, gender, and income differences where relevant and feasible.

1.2 Eligibility for support

To apply for New Vaccines Support, a country must meet GAVI eligibility criteria, determined by a country's Gross National Income (GNI) per capita for the latest available year. For 2012, the last available data is from 2010, as reported by the World Bank in July 2011. Countries are eligible for GAVI support if their GNI is equal to or less than US$ 1,520. Currently there are 57 eligible countries. GNI

[1] HPV vaccine availability is subject to manufacturers satisfying the GAVI Board requirement in relation to an acceptable price.

levels are also used to determine the level of co-financing required by GAVI. Eligible countries in 2012 are listed against their corresponding co-financing category in Annex A.

For GAVI new vaccines support, only countries with DTP3 coverage levels greater than or equal to 70%, based on the latest available WHO/UNICEF estimates, are eligible to apply. However, countries can apply for Meningitis A, Yellow fever and Measles-rubella vaccines irrespective of DTP3 coverage levels.

Access to pneumococcal vaccines for graduating countries
Graduating countries that in 2011 passed the threshold of $1,500 GNI (World Bank, 2009) and are no longer eligible to receive financial support from GAVI for new vaccines, **will continue to be able to apply for pneumococcal vaccines** through GAVI and UNICEF at the terms and conditions of the Advance Market Commitment (AMC; http://www.gavialliance.org/funding/pneumococcal-amc/). These countries should note that they will need to fully pay the vaccine co-payment of US$3.50 from the outset. Countries that have not yet applied for pneumococcal vaccines and therefore meet these criteria are: Bhutan, Cuba, Indonesia, Mongolia, Sri Lanka, and Ukraine. A simplified application process will apply.

1.3 The application and review process in 2012

The application process and corresponding timeline is summarised below:

- **Early June:** Online application form is launched for submission of NVS applications
- **31 August: Application submission deadline**
- **8-19 October:** GAVI Independent Review Committee meeting to review NVS applications
- **Early December:** GAVI Board to consider and decide on IRC recommendations

1.4 Accessing and completing the online application form

Countries will be able to apply for GAVI support through an online application form. The online application form will be launched through a GAVI web site at the start of June. At the same time, a comprehensive user guide to the online form will be made available to assist countries to navigate and complete the form. Only one form will need to be completed for the vaccine(s) requested.

An application form should be completed by the relevant ministry (e.g. Ministry of Health) in close collaboration with the Inter-Agency Coordinating Committee (ICC) or equivalent national coordinating body, as well as all other national stakeholders. The process should allow all partners to co-ordinate their support for the national immunisation programme, with all funding arrangements and programmatic issues reflected in the comprehensive multi-year plan (cMYP).

The full application and supporting documentation must be uploaded to the online form. The following list provides a summary of key requirements of the online form. A full and final list will be provided with the user guide for the online form.

Key Requirements
The following is provided as an indicative and non-exhaustive list of application requirements, intended to facilitate planning by countries and partners, and to provide an outline of the crucial details necessary for a complete application. More specifics on the requirements will be included in the online form.

General data

- The specific request for GAVI support, including duration, total amount of doses requested and details of the vaccine(s) and presentation(s) requested.
- Relevant baseline data, including DTP3 and Measles coverage data (as reported on the WHO/UNICEF Joint Reporting Form), as well as annual DTP drop-out rates.
- Information on how vaccine coverage will be monitored and reported, including through the administrative data system as well as through household surveys.
- Target(s) for the birth cohort to be covered by the new vaccine(s).
- The current vaccination schedule used in the national immunisation programme.

Vaccine introduction planning

- An Effective Vaccine Management (EVM) assessment report, or equivalent, conducted within the preceding 36 months, and corresponding improvement plan updated no more than six months prior to application submission, including an itemised account of actions taken, consistent data on cold chain capacity and readiness to accommodate the new vaccine(s), stating how the cold chain expansion, if required, will be financed, and when it will be in place.
- Countries must provide adequate data on incidence or burden of disease(s), based either on reported cases or appropriate estimate of the burden of disease, using cMYP data, if available.
- The cMYP referring to the introduction of the new vaccine(s).
- The portion of vaccine supply to be procured by the country and the portion to be procured by GAVI for the preferred vaccine(s). If a country will self-procure, details on how this will be done.
- Suitable details on how co-financing will be planned and sustained in the short to medium term.
- A satisfactory account of lessons learned from the introduction of previous new and underused vaccines in the country and actions taken in response to recommendations made after an earlier post-introduction evaluation (PIE), if applicable. WHO recommends that countries conduct a PIE within 6-12 months after the introduction of a new vaccine. If a country has completed a PIE, a summary should be submitted as part of the Annual Progress Report.

Involvement of the ICC and member signatures

- A description of the participation of stakeholders in preparing the application, including details of the ICC.
- A record of minutes of the three most recent ICC/NITAG meetings showing discussion and agreement on the application.
- The role, responsibility and functions of the ICC in relation to the implementation of all immunisation initiatives and overall health sector planning should be made clear.
- A detailed ICC work plan for the forthcoming 12 months, showing frequency of meetings, list of members, budget requirements for strengthening the ICC, if necessary.
- Members of the ICC must also sign the application form, representing their agreement and support for the information and plans provided in the application. Signature does not imply any financial or legal commitment on the part of the individual or the entity that they represent.

Signatures of ministers or their delegates

- The Minister of Health and the Minister of Finance must sign all applications.
- For HPV vaccine applications, if the chosen delivery strategy is school based, confirmation that the Ministry of Education was involved must be provided through the minutes of the ICC and/or by signature of the Minister of Education.

1.5 Checklist of mandatory documents

The following are a mandatory requirement and must be uploaded to the online application form:

- Signature of the Ministers of Heath and Finance on the proposal
- Signatures of the ICC or equivalent national entity
- Minutes of the ICC or equivalent in endorsing the proposal
- Minutes of the last three ICC meetings or equivalent
- Comprehensive multi-year plan (cMYP)
- cMYP costing and financing tool for financial analysis
- Improvement plan based on the EVM

1.6 Application assessment and approval

The application review process is conducted as follows:

i. **Completeness check:** Applications received are checked by the GAVI Secretariat for completeness and mandatory requirements. Incomplete or invalid proposals will not be submitted for independent review.
ii. **Pre-assessment:** Pre-assessment of applications is managed by the GAVI Secretariat, with a focus on validity and consistency of data and co-ordination with other sources of information.
iii. **Independent Review Committee (IRC) meeting:** The IRC reviews the applications, taking into account the pre-assessment reports. The IRC makes its recommendations to the GAVI Alliance Board or Executive Committee.
iv. **Updates to countries:** The GAVI Secretariat will inform countries of the IRC recommendations following the IRC meeting, in a short period of time after receipt of the IRC Chair's report.
v. **Approval:** The Board or Executive Committee considers and approves the IRC recommendations.
vi. **Confirmation:** A Decision Letter is sent to inform the country of the decision within a short period of time. WHO and UNICEF are also informed to facilitate preparations, including vaccine shipments.

The following table summarises each type of recommendation that can be made by the IRC:

Application Outcomes	Explanation
Recommended for approval	The application meets all criteria and is recommended for approval for GAVI support.
Recommended for approval with clarifications	The application lacks specific pieces of data. Missing requirements must be provided within a month of receipt of an official letter. Satisfactory data must be received before the application can be considered officially recommended for approval for GAVI support.
Recommended for approval with conditions	The application does not fulfil specific application requirements. Missing requirements must be provided in a subsequent application round to complement the original application. Conditional approvals will be valid for 12 months or until the next application deadline if it occurs after 12 months. If the conditions are not met within that period, submission of a new application is required.
Recommended for resubmission	The application is significantly incomplete and a full application should be submitted in a future round.

The prioritisation procedure in case of limited financial resources

In situations of limited resources, not all applications recommended by the IRC may be approved for funding by the Board. Proposals recommended for funding by the IRC are submitted to the GAVI Alliance Board or Executive Committee, which decide how many applications can be approved in the light of GAVI's available funds. The prioritisation procedure is only applied should GAVI find that its available resources are limited compared to overall demand in a particular application round. This procedure was established in order to ensure that in a situation of financial constraints, limited funds are transparently and objectively allocated to countries.

2. Application requirements

2.1 Overall assessment criteria

The GAVI Independent Review Committee will assess and evaluate the application against set criteria, ensuring that the data and information provided is satisfactory. The assessment criteria are listed below:

- Application must be submitted by the Ministry of Health, and signed by the Minister of Health, Minister of Finance and members of the Inter-agency Co-ordination Committee (ICC). For HPV applications, if the chosen delivery strategy is school based, the Ministry of Education must be involved in the ICC and/or the application must be signed by the Minister of Education.
- The cMYP, based on the Health Sector Strategic Plan and valid for at least one year from the proposed date of introduction. Support may be requested for the duration of the cMYP.
- A plan and budget for vaccine introduction, including; 1. A situation analysis of the immunisation programme including socio-economic and gender barriers; 2. Analyses of the current and future costing and financing of the programme; 3. An outline of all preparatory activities.
- An Improvement Plan, updated or developed no more than six months prior to application submission, based on the EVM, or equivalent, conducted within the preceding 36 months of submission date.
- A vaccine introduction date within two years of the application round, in this case, no later than August 2014.
- Government commitment to meet the co-financing requirements for the vaccine(s) from the year of introduction of the vaccine(s). Measles second dose within routine EPI programme, MR catch-up campaigns and preventive campaigns for Yellow fever and Men A are the only vaccines exempt from co-financing.
- Justification for the vaccine introduction, including national or regional data on disease burden, if available.
- For MR, countries must demonstrate an ability, including financial planning, to introduce and maintain rubella-containing vaccine (RCV) into the routine programme after the catch-up campaign. To demonstrate that countries can achieve and maintain immunisation coverage of 80% or greater with a RCV delivered through routine immunisation and/or regular follow-up Supplemental Immunisation Activities (SIAs), the country must have routine coverage of a measles containing vaccine (MCV1) ≥ 80%. If a country has routine coverage of MCV1 < 80%, it will need to demonstrate, for the last measles SIA, **either** administrative coverage ≥ 90%, **or** results of a survey of acceptable methodology (i.e. population based sampling) showing coverage ≥ 80%.
- For nationwide introduction of HPV vaccines, countries must identify a single year target vaccination cohort within the target population of 9-13 year old girls, and have demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district (preferably comprising urban and rural areas) using a strategy similar to the one proposed for national HPV vaccine delivery.

There are additional requirements specific to individual vaccines. For details on all requirements on a vaccine by vaccine basis, see Section 4: Vaccine Specific Considerations.

2.2 Vaccine management

Effective Vaccine Management Assessment (EVM)

Vaccine wastage must be minimised through good planning and efficient vaccine management systems, such as effective temperature monitoring. It is mandatory for a country applying for NVS to conduct an EVM assessment, including an assessment of supply chain, vaccine storage and transport capacities in the country. **The EVM assessment, or equivalent, must have been conducted within 36 months prior to the application date, in this case after August 2009.** It will remain valid to support GAVI NVS applications for three years, after which time it will need to be repeated.

A country can conduct such an assessment either on its own or seek assistance from partner organisations. The EVM and immunisation supply chain planning tools are available from WHO for guidance: http://www.who.int/immunization_delivery/systems_policy/logistics/en/index5.html.

An integral part of the EVM assessment is **the Improvement Plan** and reporting on progress of implementation of the Plan, updated within six months of application submission, which must also be included in the application documents and in the Annual Progress Report. **The GAVI IRCs for new applications and annual monitoring will pay particular attention to the Improvement Plan and reporting on progress against the plan.** The IRC needs to ensure that cold chain capacity, vaccine management and other key aspects meet the requirements for new vaccine introduction. For each area of the EVM that requires such improvements, the IRC requires an implementation plan, a timeline and budget of committed resources for these activities.

Planning and coordinating in-country

The ICC or equivalent national coordinating body, including any technical EPI advisory groups such as the NITAG, should be closely involved in the process of deciding whether to introduce a new vaccine to ensure that all information and options have been taken into account, and to guide effective integration of immunisation initiatives. The application should be prepared in close consultation with the ICC.

If an updated cMYP is not available, valid for at least one year from the proposed date of introduction, then the ICC, National Immunisation Programme team and National Health Planning Department should prepare the new updated cMYP before applying for support. Technical assistance to support this process is available through GAVI Alliance partners.

Vaccine procurement

In the procurement of vaccines and associated injection safety supplies, countries may select either:

- The supplies in kind from GAVI, procured through UNICEF or PAHO's Revolving Fund, or
- An equivalent cash grant, applicable to the GAVI portion only, in lieu of supplies and self-procure.

The second option, to select a cash grant, does **not** apply to Pneumococcal vaccines. Countries willing to introduce pneumococcal vaccines must procure through UNICEF Supply Division (SD) including the co-financed portion. For other vaccines and equipment, in the NVS application, self-procuring countries should:

- Indicate how the funds will be transferred to the country, and how vaccine and injection safety supplies will be procured and managed
- Plan their vaccine procurement and co-financing contributions in accordance with country planning and budget cycles, clearly indicating the timing of procurements in the application

If national authorities wish to use an alternative mechanism to UNICEF or PAHO's Revolving Fund for procurement and delivery of supplies (partly financed by GAVI), the country is required to submit the following information with their application:

- Description of the mechanism and the vaccines or commodities to be procured by the country
- Assurance that vaccines will be procured from the WHO list of pre-qualified vaccines, or, for the procurement of locally-produced vaccines, directly from the manufacturer provided that the vaccine has been licensed by the National Regulatory Authority (NRA) and that the NRA meets WHO published indicators for a functional vaccine regulatory system, as assessed by WHO.

After the GAVI Board or Executive Committee approves the proposal, GAVI will conduct a review of the proposed procurement mechanism to assess whether it satisfies generally acceptable procurement methods and to provide any recommendations on minimum reporting requirements and improvements.

The country will receive the total funding for the procurement in a lump-sum from GAVI only after it agrees to conform to the above-mentioned GAVI recommendations. This amount will be based on the equivalent value of the UNICEF weighted average price or estimated prices for such vaccines. If a country's negotiated procurement price is higher than UNICEF's weighted average price or estimated price, the government must pay the difference in order to purchase enough vaccines to reach the target population. If the price is lower than UNICEF's weighted average price or estimated price, the country can retain the excess funds and should report how they were used in the immunisation programme in the Annual Progress Report.

All countries may procure their co-financed portion through UNICEF or an alternative mechanism (to be specified in the application). In the former option, countries should transfer funds directly to UNICEF as outlined in the Procurement Services Memorandum of Understanding between UNICEF and the country (either to UNICEF Supply Division or to the country office). Co-financed funds should not be transferred to the GAVI Secretariat. The country agrees with the procurement agent to share information with GAVI on the status of the purchase of co-financed portion of the vaccines and supplies.

2.3 Monitoring and reporting

National authorities are required to monitor and report on the number and proportion of children in the target population immunised in a timely manner and the allocation and use of funds to co-finance the vaccines and associated injection safety materials. Monitoring will be based on submission of the following, as required by the Annual Progress Report:

- Information on progress against targets from routine monitoring systems as well as from periodic independent surveys conducted at appropriate intervals
- Reports on the management of vaccine stocks
- Reports on the use of funds on a quarterly or periodic basis
- Evidence of vaccine procurement in compliance with the co-financing agreement.

Countries are required to submit the Joint Reporting Form to WHO and UNICEF each year in a timely manner, and should conduct a Post Introduction Evaluation 6-18 months after vaccine introduction. GAVI and its Alliance partners also conduct site visits as appropriate.

In addition, countries choosing to receive cash in lieu of supplies for the procurement and delivery of vaccines and associated injection safety supplies must report in the Annual Progress Report on:

- The number and value of doses self-procured, including the co-financed option, savings made, if any, and the number of doses that have been delivered
- The national procurement principles and processes, to ensure that good procurement practices are followed. Documentation of national procurement principles and process should include a summary addressing product range, type of tender used, invitation list and criteria for invitation, tender duration, evaluation criteria and outcome of the process.
- Financial and procurement requirements agreed with GAVI

GAVI Annual Progress Reports

The receipt of satisfactory Annual Progress Reports (APRs) is a condition for the continuation of any form of GAVI support. The Government is responsible for annual submission of ICC-endorsed APRs by a **deadline of 15 May each year.** All APRs are reviewed by the Monitoring IRC. The APR must be submitted together with the minutes of the ICC meetings of the reporting year. The report must contain information on progress in implementation, coverage, co-financing commitments and payments. Further guidelines on APRs are available on the GAVI website. Both the NVS application and APR must be submitted electronically.

Changes in introduction plans and/or coverage

Countries should communicate significant changes in plans to the GAVI Secretariat and UNICEF SD. Changes may include accelerated or delayed introduction or increases or decreases in vaccine use. Revised plans should be communicated through the APRs, however, urgent matters, especially those impacting vaccine shipment quantities, should be brought to the attention of the GAVI Secretariat and UNICEF SD outside of the schedule of Annual Reports.

Changes in presentation of a vaccine

After approval for support, a country may wish to change the original formulation and/or presentation of a vaccine containing the same antigen, (e.g. from lyophilised pentavalent to liquid pentavalent or to a different number of doses per vial). In such cases the introduction plan and cMYP should be updated, reviewed and endorsed by the ICC to ensure that it addresses issues such as cold chain and storage capacity as well as the relevant in-service training plans for health providers. The information should then be included in the Annual Progress Report and submitted to the GAVI Secretariat which determines if it is consistent with the previous approval. UNICEF Supply Division will advise if and when the revised request can be accommodated after reviewing the vaccine stocks of current formulation being used in a country and availability of the vaccine presentation requested.

Due to high demand in the early years of introduction, requests for switch of pneumococcal or rotavirus vaccine presentation (PCV10 or PCV13; rotavirus two-dose or three-dose) will not be considered.

Countries can apply (through the APR or if urgent on an ad hoc basis via a letter to GAVI and the procurement partner) for an additional grant to facilitate transition to a new product for an existing antigen if specific criteria are met. See section 3.1 for an overview of the introduction grant policy.

Monitoring vaccine stocks and wastage

Countries are required to report on in-country vaccine stocks in the APR. Approval of the original quantity of doses in the proposal will not automatically translate into the supply of the same quantity. Should these quantities not be needed due to reduced uptake or utilisation or other reason, GAVI will issue a new communication in case of change in quantities approved for a country. Also, in the APR,

countries are expected to report on the specific wastage rate of the vaccine(s) that have been introduced with GAVI support.

Waste management
Countries are strongly encouraged to have a waste management plan as appropriate for their immunisation activities. This should include details on the safe handling, storage, transportation and disposal of immunisation waste, as part of a healthcare waste management strategy.

2.4 Financial requirements

Financial management
The GAVI Alliance adopted a Transparency and Accountability Policy (TAP) for cash-based support, with effect as of 1 January 2009. Cash-based support is provided through the NVS introduction grant or if a country requests cash in lieu of supplies.

The TAP outlines the minimum requirements for financial management of cash support. Funds must be:

- Used for immunisation services
- Managed in a transparent manner, and accurate and verifiable financial reports must be provided on a regular basis
- Managed in accounts meeting national requirements for auditing, accounting and procurement
- Subject to an independent external audit
- Subject to scrutiny by the GAVI TAP team through Financial Management Assessments (FMAs) when cash-based support is provided in lieu of supply.

Besides these minimum financial management requirements, funds must be:

- Reflected in the national budget
- Additional to the government allocation to immunisation services, as well as to the contributions of other partners: i.e. no funding should be diverted away from immunisation services after receiving GAVI support
- Subject to an oversight by the in-country Inter-agency Coordination Committee (ICC) along with other funds for immunisation services.

The use of cash support provided through the introduction grant and operational support for campaigns must be reported in the APR. Amounts of $250,000 or more require mandatory audits when these funds are directly disbursed to the country. 25% of grants below $250,000 will be randomly selected for audit. Therefore all countries will need to maintain adequate books and records for these amounts.

Audit
The GAVI Transparency and Accountability Policy (TAP) establishes that all countries receiving cash support should submit an external audit report, for example an Auditor General's Report or a report from Independent External Auditors , of the account(s) holding the GAVI funds within six months of the close of the financial year. GAVI is now involved through its TAP Team in the drafting of Terms of Reference for such external audits in order to ensure that the audit work meets quality requirements and effectively addresses key risk areas. GAVI reserves the right to request an external audit of the accounts at any time during or after the duration of the GAVI support. GAVI in-country partners and the ICC members can communicate any concerns they might have about the use of funds to the GAVI Alliance Secretariat at any time.

2.5 Co-financing requirements

The objective of the co-financing policy is to increase country ownership of vaccine financing and ensure that countries are on a trajectory towards financial sustainability, in order to prepare for phasing out GAVI support. The co-financing requirements of a country should be included in the application and in the corresponding cMYP. All countries are expected to co-finance at the minimum levels described below and higher contributions are encouraged to facilitate achievement of financial sustainability.

All countries are required to co-finance the GAVI supported vaccines from the time of introduction. Co-financing levels for all vaccines are per dose, except for co-financing the rotavirus three-dose schedule which is adjusted to equal the co-financing contribution of the two-dose schedule.

The only **exceptions from co-financing** are vaccines for measles second dose, Men A and Yellow fever preventive campaigns and measles-rubella.

For co-financing purposes, GAVI-eligible countries are grouped into three categories, based on the 2010 GNI per capita data (released by the World Bank in July 2011). **The country co-financing groups, GNI thresholds and list of countries with their corresponding co-financing requirements for 2012 is provided in Annex A.**

Timeline for co-financing implementation

Co-financing group thresholds are updated annually in September, based on the GNI per capita data released by the World Bank every year in July. Countries will then be informed of any changes to their co-financing group and will have just over one year after this communication to revise budgets and begin co-financing at the new level.

The fulfilment of the co-financing requirements is related to the country's procurement of the number of doses stipulated in the decision letter or the corresponding dollar amount for vaccines (excluding handling fees, freight, and buffer charges). For self-procuring countries, compliance is defined by the purchase of the number of doses indicated in the decision letter.

In 2014, GAVI will review the co-financing policy and any changes will be communicated thereafter.

Co-financing default

A country enters into default status when it has not fulfilled its co-financing commitment by 31 December of a particular year, e.g. 2013 co-financing must be paid in full by 31 December 2013. If a country remains in default for more than one year, the GAVI Board may suspend support for the vaccine(s) in question until the co-financing arrears are paid in full.

If a country is at risk of entering into default status, it will receive a reminder letter from GAVI in the fourth quarter of a year. If a country is then entering into default status, the following actions are taken:

- At the start of the next year, the GAVI Secretariat will inform the country of its default status
- GAVI partners at regional and country levels work with the country to fulfil its requirement
- New applications may be submitted, but approval is contingent on the fulfilment of its co-financing requirements. New vaccines cannot be approved if a country is in default.
- If a country remains in default for more than one year, support for the specific vaccine(s) in question will be suspended following GAVI Board decision until the co-financing arrears are paid in full

3. Vaccine introduction

3.1 The vaccine introduction grant and operational support for campaigns

The GAVI Alliance recently proposed changes to the vaccine introduction grant policy that were reviewed and approved by the GAVI Board at its meeting in June 2012. This policy comes into effect as of 01 September 2012 and will apply to all new introductions and campaigns taking place after this date.

When countries have been approved for a new vaccine, they will also receive a one-time cash grant to support a share of the additional costs, with the remainder being funded by the Government. This is on the basis that the country meets the financial management requirements outlined in section 2.4.

Vaccine introduction grant
The aim of GAVI's vaccine introduction grant is to facilitate the timely and effective implementation of critical activities in the national vaccine introduction plan in advance of a new vaccine introduction.

Pre-introduction activities that can be funded through the GAVI vaccine introduction grant may include but are not limited to health worker training, information, education and communication (IEC) and social mobilisation, microplanning, expansion or rehabilitation of some cold chain equipment and additional vehicles if needed, printing and purchase of materials (such as immunisation cards), technical assistance, and modifications to the surveillance systems. The government is encouraged to work with civil society organisations and other in-country partners to determine how these activities are best carried out.

What are the new funding levels?

	GAVI support	NVS Vaccines for routine
Vaccines delivered to infants	**$0.80** (per child in the birth cohort) Or lump sum **$100,000**	Pentavalent, Rotavirus, Pneumococcal, Measles Second Dose, Rubella routine, Yellow Fever routine, MenA routine
HPV vaccines	**$2.40** (per girl) Or lump sum **$100,000**	HPV

Operational support for campaigns
The aim of GAVI's operational support for campaigns is to facilitate the timely and effective delivery of vaccines to the target population.

In addition to the pre-introduction activities outlined above, the following types of expenses may also be included: volunteer incentives for vaccine delivery or monitoring, health workers and supervisor per diems, cold boxes and ice packs, transport, monitoring and evaluation and civil society organisation and/or volunteer incentives for social mobilisation.

What are the new funding levels?

	GAVI support	NVS Vaccines for campaigns
All campaign vaccines	**$0.65** (per target person)	MenA campaign Yellow Fever campaign Measles Rubella campaign

What are the pre-requisites to obtain the grant?
In order to obtain this grant, countries must define the activities they plan to conduct, the budget detailing the full non-vaccines cost (in line with the vaccine introduction plan) and activities for which the grant will be used. The application form contains specific tables that must be completed in relation this support. For activities not covered by the grant, countries should indicate a budget and an alternate source of funding. Countries must also report on the use of the grants in their annual progress reports to GAVI.

3.2 Readiness for introduction

GAVI is working closely with countries and their partners to more effectively assess any technical support requirements with respect to the pre-introduction preparations. Accordingly, GAVI is looking to establish a greater level of engagement with countries following confirmation of vaccine approval.

Should a country require any type of technical support for pre-introduction preparations, please contact your GAVI focal point in the Secretariat or the local WHO office.

Due to a variety of factors, the launch date may vary compared to the date stipulated in the application. Similarly, data on the target population for the vaccine(s) may differ compared to the data included in the application. GAVI will work very closely with countries and their partners to address these issues.

3.3 Vaccine preferences and timing of supply availability

Vaccine preferences
The online application form will request the country to rank their first, second and third preference of vaccine presentation, if appropriate. The country should substantiate the choice of first preferred presentation. If a case arises that the first preference of vaccine is in limited supply or not available in the short term, GAVI will contact the country and partners to explore alternative options. A country will not be obliged to accept its second or third preference, however GAVI will engage with the country to fully explore a variety of factors (such as implications on introduction timing, cold chain capacity, disease burden, etc.) which may have an implication for the most suitable selection of vaccine. If a country does not indicate a second or third preference, it will be assumed that the country prefers to delay introduction until the first preference is available. It should be noted that this may delay the actual introduction in the country.

For information on vaccine presentations, please consult the UNICEF Product Menu at
http://www.unicef.org/supply/index_gavi.html

Supply availability
Given the unprecedented scale up of demand for GAVI supported vaccines, some countries may have to introduce the vaccines later than planned. This is mainly due to the lead time required by manufacturers to increase vaccine production. As a result, the global vaccine supply will not meet all country requirements in the short term.

Countries submitting an application in 2012 to be approved for **pneumococcal or rotavirus vaccines** will not be able to introduce the vaccine until 2014 at the earliest.

If the introduction date is postponed, the number of years of approved GAVI support will remain unchanged, irrespective of any graduation from GAVI support. Further, the requirement to co-finance the vaccine will begin only once the supply commences.

GAVI is making all efforts to limit the number of countries affected by supply constraints and to reduce the length of the delay. We are carefully monitoring countries' vaccine preferences and readiness to introduce, and working closely with manufacturers to explore all options for best use of the available supply.

4. New vaccines support

4.1 Vaccine specific considerations

Information resources
Information on vaccine-preventable diseases and new and underused vaccines supported by GAVI is available from www.who.int/immunization, www.who.int/nuvi, and from www.gavialliance.org. Updated supply information on suppliers, product formulations and presentations, prices and cold chain requirements are available from UNICEF Supply Division: http://www.unicef.org/supply/index_gavi.html or by contacting UNICEF Supply Division or the GAVI Secretariat.

Countries that are eligible for support for Yellow fever or Men A preventive campaigns and are interested in applying are recommended to contact the local WHO office for more detailed information on the GAVI Alliance support available.

Pentavalent, Pneumococcal and Rotavirus vaccines
The WHO Strategic Advisory Group of Experts on Immunisation (SAGE) recommends vaccines against Hepatitis B, *Haemophilus influenzae* type b (*Hib*), *Streptococcus pneumoniae* and Rotavirus for global use. GAVI support for these vaccines is for routine infant immunisation, in line with WHO recommendations and primarily targeting children under one year of age. Support is not available for a "catch up" campaign for these vaccines.

The following should be considered when applying:

- **DTP-HepB-Hib (Pentavalent)** vaccine: Available in a liquid and a liquid/lyophilised formulation in vials of 1, 2 and 10 doses, to be used in a three dose schedule.
- **Rotavirus** vaccine: Available in an oral monovalent vaccine in a two-dose schedule and an oral pentavalent vaccine in a three-dose schedule
- **Pneumococcal** vaccine: Available in a liquid formulation in a one dose vial (13-valent) and a two dose vial (10-valent). Both formulations are to be used in a three-dose schedule.

Further information on the different vaccines is available on the WHO website as follows:

- Hepatitis B vaccine: www.who.int/immunization/topics/hepatitis_b/en/index.html
- *Hib* vaccine: http://www.who.int/nuvi/hib/en/index.html
- Pneumococcal vaccine: http://www.who.int/nuvi/pneumococcus/en/index.html
- Rotavirus vaccine: http://www.who.int/nuvi/rotavirus/en/index.html; http://www.who.int/immunization/topics/rotavirus/en/index.html

Yellow fever vaccine for routine use
The GAVI Alliance will only support countries where at the time of application, yellow fever vaccine coverage is lower than measles vaccine coverage based on the latest WHO/UNICEF coverage estimate for both vaccines.

Yellow fever vaccines for preventive campaigns
A preventive campaign with Yellow fever vaccine significantly reduces the risk of the disease and the occurrence of epidemics. The campaign is recommended for the entire population above nine months of age.

GAVI will provide US$ 0.65 per individual in the target population of the campaign to help cover operational costs (expected to cover approximately 80% of the total estimated cost). The support will be provided in cash through WHO and UNICEF. Countries must meet the remaining operational expenses for the campaign.

Meningococcal A conjugate vaccines for preventive campaigns

To reduce the risk of Meningococcal A meningitis epidemics in the 26 most-affected countries in Africa, a one-time preventive campaign with Men A vaccine is recommended in the population aged from one to 29 years old. See Annex A for a list of eligible countries. GAVI will fully fund the vaccine needs for the preventive campaigns.

GAVI will provide US$ 0.65 per individual in the target population of the campaign to help cover operational costs (expected to cover approximately 80% of the total estimated cost). The support will be provided in cash through WHO and UNICEF. Countries must meet the remaining operational expenses for the campaign.

Once announced by GAVI, the campaigns will be followed by the introduction of Men A into the routine vaccination schedule in the following years, at which time GAVI will provide funding for the introduction of Men A vaccine in routine immunisation. As with other vaccine introductions, the country will have to co-finance the cost of Men A vaccine introduction into the routine vaccination schedule.

Measles vaccine second dose (MSD) through routine immunisation

GAVI will provide support for countries to introduce a second dose of measles-containing vaccination into their routine immunisation programme, if this introduction is included in the country's cMYP and the country has routine measles first dose coverage greater than 80% as documented by WHO/UNICEF estimates or well-conducted coverage surveys. Countries are not expected to co-finance measles second dose (MSD) introduction into routine vaccination. Support for the measles vaccine and associated injection safety materials is for a period of five years and available in kind or in the form of cash. Support in the form of cash will be equivalent to the cost of the measles vaccine doses and injection safety materials, based on the UNICEF weighted average price (WAP) for a 10 dose measles monovalent presentation, including freight and insurance charges. When support is in the form of cash a country can use the cash funds from GAVI for the procurement of a measles-containing vaccine, either monovalent or combined with other antigens in line with the requirements for self-procurement outlined above in section 2.2.

Measles Rubella (MR) vaccine

The WHO rubella vaccine position paper recommends that countries take advantage of the measles platform of two doses of measles vaccine to introduce rubella-containing vaccine (RCV) as either measles-rubella (MR) or measles-mumps-rubella (MMR) vaccine. The WHO position paper recommends the strategy of conducting a wide age-range catch-up campaign, followed immediately by introduction of MR vaccine in the routine programme. Countries should give MR at the same age as they currently give the first dose of measles-containing vaccine (MCV) in the routine schedule. WHO global recommendations for rubella include: 1) catch-up campaign; 2) routine childhood vaccination incorporating RCV with the first dose of MCV (MCV1); 3) regular follow-up campaigns with MR-

containing vaccines, in countries with MCV1 coverage less than 90-95%; 4) efforts to reach women of childbearing age; and 5) surveillance for rubella and congenital rubella syndrome (CRS).

GAVI will provide support to countries for rubella catch-up campaigns by providing MR vaccine for a target population of males and females aged 9 months to 14 years (the exact age range will depend on rubella epidemiology in the country). GAVI will finance the costs of the bundled vaccine, including AD syringes, reconstitution syringes and safety boxes. As a share of the operational costs for the children and adolescent campaign, GAVI will provide US$ 0.65 per individual in the target population of the campaign to help cover operational costs (expected to cover approximately 80% of the total cost). Countries are also eligible for a vaccine introduction grant to facilitate activities in the first year of MR introduction into routine immunisation; see section 3.1 for more information. GAVI will not provide support for rubella-containing vaccines for routine immunisation services.

The GAVI Alliance will continue to fund applications for measles second dose through routine immunisation services in conjunction with the support for introduction of MR. If countries applying for measles second dose through routine immunisation services opt to provide the second dose as MR, they will be required to finance the rubella component (although eligible countries will be able to buy either monovalent or combined with other antigens). For countries that have 2 doses of MCV in their routine schedule, only one dose of RCV is necessary and it should be administered with the MCV1, so, single antigen measles vaccine would be acceptable as a second dose of MCV. For programmatic and logistical reasons, it is preferable (but not required) that the country uses one type of MCV. For countries still conducting follow-up campaigns, MR vaccine should be used in both campaigns and routine.

Countries must provide the following to meet the criteria to be considered for RCV:

1. **Evidence that the country can achieve high immunisation coverage**
   According to the WHO Position Paper, once countries have introduced RCV, they should achieve and maintain immunisation coverage of 80% or greater through routine immunisation and/or regular follow-up SIAs. To demonstrate their ability to achieve this, countries must show either:
   a. Routine MCV 1 ≥ 80%, or
   b. If a country has routine coverage of MCV1 < 80%, it will need to demonstrate, for the last measles SIA, **either** administrative coverage ≥ 90%, **or** results of a survey of acceptable methodology (i.e. population based sampling) showing coverage ≥80%.

2. **Evidence that the country can finance the introduction of RCV in their routine programme**
   For MR, GAVI support is for the initial catch-up campaign and a vaccine introduction grant (GAVI will not provide RCV for routine use). Countries must demonstrate an ability, including financial planning, to introduce and maintain RCV in the routine programme. To ensure that countries will introduce RCV into the routine programme, evidence of intent to purchase MR/MMR vaccine should be provided, including but not restricted to:
   - A commercial contract for purchase of MR/MMR vaccine together with shipping documents, invoice, etc.
   - RCV being integrated into the cMYP with the budget line for vaccines increased to include purchase of RCV as part of the health sector budget to indicate that RCV funds are allocated
   - A letter from the Minister of Finance or Budget ensuring additional funding for RCV purchase
   - An MOU between government and donor(s) (or other written document that proves donor commitment) for at least one year for purchase of RCV for use in the routine programme

In addition, countries should provide information on epidemiology and disease burden and introduction planning:

1. Epidemiology and disease burden

Countries should provide a rationale for introduction of RCV using available disease burden data. If countries do not have national rubella and/or CRS data, they should plan to establish systems or conduct studies to collect this data and stipulate these activities in the Plan of Action (POA) for RCV introduction. Countries should also provide rationale for their target age range for the catch-up campaign as well as the proposed age for administration of MR or MMR vaccine in the routine immunisation schedule. Information sources should include:

- Epidemiological information on burden of disease:
  - i. Rubella data from the measles case-based surveillance system (including the age distribution of rubella cases)
  - ii. Rubella seroprevalence surveys
  - iii. CRS burden information, e.g. retrospective search, modelled estimates for CRS burden, prospective surveillance
- Coverage data: Both routine and SIA coverage data should be provided from 2005 to the present. For routine coverage, countries should report coverage for MCV1 and MCV2 (if given through routine vaccination services) for each year since 2005 (both national reported administrative coverage and WHO/UNICEF estimates). For SIAs, countries should report coverage including results of coverage surveys and administrative coverage for all nationwide measles campaigns conducted since 2005.

2. Introduction planning:

Countries should describe their plans for introduction including surveillance activities:

- Comprehensive plan for the introduction of RCV into the national programme. Countries should provide both the POA and cMYP including an approved addendum to the cMYP. However, countries that have revised their cMYP within the last year and have not included RCV introduction in the cMYP should submit the POA but provide a timeline for updating the cMYP.
- Components of the POA/cMYP should include:
  - a. Comprehensive vaccination strategy for the introduction of RCV including a description of:
    - i. Initial MR campaign
    - ii. Replacing MCV with MR / MMR in the routine childhood vaccination programme
    - iii. Strategies for targeting Women of Childbearing Age (WCBA), such as vaccination during routine services, post-partum, at 1st well baby visit, SIAs.
    - iv. Linkage to the current routine immunisation schedule
    - v. Linkage to measles second dose, if applicable
    - vi. Description of how the country plans to continue to maintain high MR/MMR vaccine coverage either through routine immunisation or through SIAs
  - b. A brief description of the following surveillance activities:
    - i. Integration of Rubella surveillance with case-based measles surveillance
    - ii. CRS surveillance or plans to establish sentinel site CRS surveillance
    - iii. AEFI surveillance
  - c. Vaccine coverage monitoring and reporting
  - d. The communication strategy for the introduction of RCV.

Even though not a requirement, countries are requested to provide information on the following indicators of the quality of measles surveillance for at least two years prior to application:

1) Reporting rate at national level (number of discarded measles cases per 100,000 population per year, target: >2 discarded measles cases/100,000 population/yr)
2) Laboratory confirmation rate (no. of suspected cases with specimens collected for testing divided by the number of suspected cases not confirmed through epidemiological linkage; target: >80%)

HPV vaccine

A WHO position paper on cervical cancer (2009) recommends that routine HPV vaccination be included in national immunisation programmes provided that: prevention of cervical cancer or other HPV-related diseases, or both, constitutes a public health priority; vaccine introduction is programmatically feasible; sustainable financing can be secured; and the cost-effectiveness of vaccination strategies in the country or region is considered. HPV vaccines should be introduced as part of a coordinated strategy to prevent cervical cancer and other HPV-related deaths.

With regards to delivery strategies, WHO recommends that countries use approaches that are compatible with their health delivery infrastructure and cold-chain capacity; that are affordable, cost-effective and sustainable; and that achieve the highest possible coverage. Priority should be given to strategies that include populations who are likely to have less access to screening for cervical cancer later in life. Opportunities to link vaccine delivery to other health programmes targeting young people should be explored. In relation to this, countries choosing to deliver HPV vaccine via schools are encouraged to leverage the opportunity offered by vaccine introduction to strengthen other school based health programmes in line with the joint UNESCO, UNICEF, WHO and World Bank recommendation for effective school health and nutrition programmes: for more information see: http://www.unicef.org/lifeskills/files/FreshDocument.pdf

To apply for nationwide introduction of HPV vaccines through GAVI, the country must:

- Identify a single year target vaccination cohort within the target population of 9-13 year old girls.
- Have demonstrated ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district (preferably comprising urban and rural areas) using a strategy similar to the one proposed for national HPV vaccine delivery.
- Provide a report on the costing analysis of the proposed delivery strategy or strategies and evidence of non-GAVI resources to support delivery.

All applications for HPV vaccine, proposing to use a school based strategy for HPV vaccine delivery:

- The minimal proportion of girls of the target vaccination cohort or target grade that is enrolled in school must be 75%.
- If the strategy targets girls enrolled in a selected grade, the majority of girls must be between the ages of 9-13 with no more than 20% of the girls aged 14 or above.
- A strategy for vaccinating girls not in school must also be planned and described, including definition of eligibility criteria.

It should also be noted that:

- Given that HPV vaccines are targeted to adolescent girls, countries will be requested to clarify how their plans for communication and social mobilisation reflect the unique needs of the programme, including key messages and mechanisms for reaching the priority audiences.

- Countries should provide a description of health services and/or health education currently provided to younger adolescents within the 9-13 year old age group.
- Where possible, countries should provide an assessment of the cervical cancer burden and status of cervical cancer prevention and control activities. Also, if available, countries should provide a national strategy, or roadmap to develop a strategy, for a comprehensive approach to cervical cancer prevention and control.
- For countries choosing to deliver HPV vaccine via schools additional information will be required describing the educational system for girls and existing school-based health programming. Documentation that Ministry of Education is a member of the Inter-agency Coordination Committee (ICC) and/or the Minister of Education's signature is also needed on the application.
- All the technical elements which are common to any vaccine introduction and need to be addressed as a standard component of a GAVI application are also necessary for an HPV vaccine application.

Countries that are unable to demonstrate an ability to immunise 9-13 years old girls, but wishing to introduce HPV vaccines, will soon have the opportunity to apply for HPV demonstration projects. Applications for demonstration projects are not yet accepted. GAVI is working with its technical partners to define the terms and conditions of the HPV demonstration programme with the objective of opening a round of applications in Q3 2012. GAVI will keep countries informed on the timeline and requirements for the demonstration programme. Please contact your GAVI focal point if you would like to indicate interest in submitting a future application for a HPV demonstration project.

For national introduction of HPV vaccines, an introduction grant of US$ 2.40 per girl is available as a one-time GAVI investment to cover a share of necessary activities in advance of the introduction (see Section 3.1 for more information). It should be noted that for HPV, as well as for any other routine NVS, GAVI will not provide any financial support for recurrent operational costs related to vaccine administration. Countries should be aware that available estimates quantify HPV operational costs as higher than recurrent costs for other GAVI vaccines. Countries are therefore encouraged to seek other national or partners' financial resources to cover these costs. The required report on the costing analysis of the proposed delivery strategy should provide evidence of these non-GAVI resources to support delivery. Countries may wish to seek technical assistance and to make use of the WHO Cervical Cancer Prevention and Control Costing Tool in order to plan delivery strategies and to estimate the resources needed to introduce and sustain vaccine delivery.

The two currently available and WHO-prequalified vaccines are; 1) a bivalent vaccine with a 0, 1 month, and 6 month schedule that prevents precancerous cervical lesions from HPV types 16 and 18, and; 2) a quadrivalent vaccine with a 0, 2 month, and 6 month schedule that prevents both precancerous cervical lesions from HPV types 16 and 18 and anogenital warts from HPV types 6 and 11. HPV types 16 and 18 cause about 70% of all cervical cancers. The vaccines may have partial efficacy against infections caused by other HPV types, including HPV types 31 and 45. Because up to 30% of all cervical cancers are caused by non-vaccine HPV types, these vaccines do not eliminate the need for cervical cancer screening.

Further information on the different vaccines is available on the WHO website at http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html and resources are available on http://www.who.int/nuvi/hpv/en/index.html

Annex A: Eligible countries and co-financing groupings

1. Countries eligible for GAVI new vaccines support in 2012.

This list of countries is based on the Gross National Income (GNI) eligibility threshold for the latest available year (2010), as reported by the World Bank in July 2011.

In addition to the GNI threshold, only countries with DTP3 coverage greater than or equal to 70%, based on the latest available WHO/UNICEF estimates, are eligible to apply for New Vaccines Support.

- Afghanistan
- Bangladesh
- Benin
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Central African Republic
- Chad
- Comoros
- Congo, Dem Republic of
- Côte d'Ivoire
- Djibouti
- East-Timor
- Eritrea
- Ethiopia
- Gambia
- Ghana
- Guinea
- Guinea Bissau
- Haiti
- India
- Kenya
- Korea, DPR
- Kyrgyz Republic
- Lao PDR
- Lesotho
- Liberia
- Madagascar
- Malawi
- Mali
- Mauritania
- Mozambique
- Myanmar
- Nepal
- Nicaragua
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Rwanda
- São Tomé e Príncipe
- Senegal
- Sierra Leone
- Solomon Islands
- Somalia
- Republic of Sudan
- South Sudan
- Tajikistan
- Tanzania
- Togo
- Uganda
- Uzbekistan
- Viet Nam
- Yemen
- Zambia
- Zimbabwe

2. Countries eligible for Meningococcal preventive campaigns

Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Cote d'Ivoire, DRC, Eritrea, Ethiopia, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Mali, Mauritania, Niger, Nigeria, Rwanda, Senegal, Republic of Sudan, South Sudan, Tanzania, Togo, Uganda

3. Co-financing groupings in 2012

The following table shows the countries eligible to apply for New Vaccines Support in 2012 (World Bank GNI equal to or less than US$ 1,520), grouped according to their co-financing requirement.

Co-financing group thresholds are updated annually in September, based on the GNI per capita data released by the World Bank every year in July. Countries will then be informed of any changes to their co-financing group and will have at least one year after this communication to revise budgets and begin co-financing at the new level.

Group	GNI per capita (World Bank) threshold in 2012	Countries (South Sudan to be added when GNI data is published.)	Amount
Low income countries	At or below $1,005, the World Bank low income threshold.	Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, CAR, Chad, Comoros, Congo DR, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kenya, Korea D.R., Kyrgyz Republic, Madagascar, Malawi, Mali, Mozambique, Myanmar, Nepal, Niger, Liberia, Rwanda, Sierra Leone, Somalia, Tajikistan, Tanzania, Togo, Uganda and Zimbabwe	**US$ 0.20 per dose. There is no annual increase.**
Intermediate countries	Above $1,005 but below the GAVI eligibility threshold of $1,520.	Cameroon, Cote d'Ivoire, Djibouti, Ghana, Mauritania, Nicaragua, Nigeria, Lao PDR, Lesotho, Pakistan, Papua New Guinea, Sao Tome and Principe, Senegal, Solomon Islands, Republic of Sudan, Timor Leste, Uzbekistan, Vietnam and Yemen and Zambia	**Starts at US$ 0.20 per dose and increases by 15% annually**
Graduating countries	Above the GAVI eligibility threshold of $1,520.	Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Congo Rep., Cuba, Georgia, Guyana, Honduras, Indonesia, Kiribati, Moldova, Mongolia, Sri Lanka and Ukraine **These countries are still receiving GAVI support, but are no longer eligible to apply for NVS in 2012, with the exception of countries which continue to be able to apply for pneumococcal vaccines through GAVI and UNICEF at the terms and conditions of the Advance Market Commitment.** **See section 1.2 for details on eligibility.**	**Starts at 20% of the projected price of the vaccine in the year GAVI support ends, and increases linearly over four years to reach the projected price.**

Annex B: GAVI Alliance terms and conditions of support

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

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 TRANSPARENCY 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.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.