



GUIDELINES ON COUNTRY PROPOSALS

For Support for:

New and Underused Vaccines

Applicable for Proposal Round:

June 2011

Application Deadline

15th May 2011

Acronyms and Abbreviations

AD	Auto-disable (syringes)
AMC	Advance Market Commitment
APR	Annual progress report
cMYP	Comprehensive multi-year plan for immunisation
CSO	Civil society organisation
DTP3	Diphtheria-Tetanus-Pertussis, 3 rd 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	<i>Haemophilus influenzae</i> type b
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
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)
RVV	Rotavirus vaccine
SAGE	WHO Strategic Advisory Group of Experts
TAG	Technical Advisory Group
TT	Tetanus Toxoid
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WAP	Weighted average price
WHO	World Health Organization

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1 Overview of GAVI New Vaccines Support

This document provides information on the support available from the GAVI Alliance for the introduction of new and underused vaccines (NVS). It provides detailed information on the eligibility criteria and the application processes to assist countries to submit proposals for the **2011 application round**. Information on the deadlines for applications and the application forms can also be found on the GAVI Alliance website in the section 'Support we offer': www.gavialliance.org/support/

New and underused vaccine support (NVS)

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

- Pentavalent vaccine (DTP-Hep B-Hib)
- Measles second dose
- Pneumococcal
- Rotavirus
- Yellow fever (routine)
- Yellow fever preventive campaigns
- Meningococcal A conjugate vaccine (Men A) preventive campaigns and routine

All countries applying for GAVI NVS are required to co-finance the GAVI supported vaccines from the time of introduction. The only exceptions for co-financing are:

- Measles second dose
- Preventive campaigns for Men A and Yellow fever

Focus on equity and gender

To attain MDGs 3, 4 and 5 there is a need to address gender and social inequalities 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 gender- and social-related barriers to access and delivery. Through its Gender Policy, the GAVI Alliance is committed to addressing these barriers in order to increase universal vaccination coverage. The Policy focuses on 1) generating, reporting and analysing new evidence, 2) ensuring gender sensitive policy and funding support, 3) advocating for gender equality as a means to improve immunisation coverage and access to health services, and 4) introducing gender sensitive approaches in GAVI Alliance structures. This includes disaggregating data, including information on geographic, gender, and income differences where relevant and feasible.

1.1 Eligibility for Support and Assessment Criteria

<i>Overall eligibility</i>
<p>Only national governments can apply¹</p> <p>Country has to be GAVI-eligible, i.e. GNI per capita (World Bank data) for latest available year equal to or less than US\$ 1,500 (data for 2009 is given in Annex A)</p> <p><u>Exceptionally for the June 2011 proposal round only, graduating countries (whose GNI per capita exceeds \$1,500 in 2009) can also apply for new and underused vaccine support</u></p>
<i>General assessment criteria for approval of country proposals for support</i>
<p>1. Application submitted by Ministry of Health, and signed by Ministry of Finance and Inter-agency Co-ordination Committee (ICC)</p> <ul style="list-style-type: none">• 2. A comprehensive Multi-year Plan for Immunisation², synchronised with the Health Sector Strategic Plan³ and valid for at least one year from proposed date of introduction <p>including:</p> <ul style="list-style-type: none">• A situation analysis of the immunisation programme including social and gender-related barriers to health• Analyses of the current and future costing and financing of the programme <p>3. An Improvement Plan based on Effective Vaccine Management Assessment (EVM)⁴ conducted within the preceding 36 months of submission date (May 2011)</p> <p>4. A satisfactory Annual Progress Report submitted reporting on the utilisation and management of GAVI support (vaccines, cash) is a condition for continuation of support</p>
<i>Specific assessment criteria for approval of country proposals for support</i>
<p>1. National DTP3 coverage over 50% (WHO/UNICEF estimates for 2009) except for Yellow fever and Meningococcal A vaccine (Men A) applications</p> <p><u>The DTP3 coverage filter will be increased to 70% after the June 2011 proposal round.</u></p> <p>2. An introduction date for the vaccine <u>within two years of the application round (e.g. by June 2013)</u></p> <p>3. A vaccine that is not already introduced in the routine schedule with national resources financed</p> <p>4. Agreed co-financing of the vaccine by Government from the onset of support.⁵</p> <p>5. Plan and budget for the introduction of the new vaccine, including preparatory activities (within the cMYP)⁶</p> <p>6. Justification for new vaccines introduction, including national or regional data on disease burden, if available</p>

¹ For countries in complex emergency situations exceptions may apply.

² WHO-UNICEF guidelines for developing a comprehensive Multi-Year Plan for immunisation including the Annex for financial analysis are available from the following website: www.who.int/immunisation_financing/tools/cmyp/en/index.html

³ The Comprehensive Multi-Year Plan for Immunisation should be synchronized with the relevant strategic document for national planning of the Ministry of Health, whether it is called the Health Sector Strategic Plan, Five Year Development Plan, or equivalent.

⁴ or equivalent (e.g. VMA or EVSM)

⁵ Measles second dose introduction within routine EPI and preventive campaigns for Yellow fever and Men A are the only vaccines exempt from co-financing.

⁶ If the current cMYP does not include a plan for introduction of the new vaccine(s), countries can submit the plan as an annex, endorsed by Government and ICC.

1.2 Financial Management Requirements

Financial Management

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

The Transparency and Accountability Policy outlines a set of minimum requirements for the financial management of GAVI support:

- a) Funds must be used for the strengthening of immunisation services;
- b) Funds must be managed in a transparent manner, and accurate and verifiable financial reports must be provided on a regular basis; and
- c) Funds must be managed within accounts that meet national legal requirements for auditing, accounting and procurement.

Besides these minimum financial management requirements:

- a) Funds should be reflected in the national budget (be on budget); and
- b) Funds should be 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.

Audit

Unless other procedures have been stipulated in a Financial Management Assessment (FMA) Aide Memoire, GAVI should receive external audit reports (e.g. Auditor General's Report or equivalent) of the account(s) holding the GAVI funds within one year of the close of the financial year. GAVI reserves the right to request that an external audit of the accounts be conducted 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 New and Underused Vaccine Support

2.1 Principles of Support

The principles of the GAVI New and Underused Vaccines Support (NVS) support are to catalyse:

- Accelerated introduction of life-saving new and underutilized vaccines
- Evidence-based national decision-making processes and endorsement by relevant national decision-making bodies such as NITAG, ICC
- The financial sustainability of national immunisation programmes, including co-financing for new and underused vaccines; and
- The alignment and integration of support with national planning and budgeting processes and timelines

Countries can apply for GAVI support to introduce one or more of the vaccines listed above. There is no limit to the number of vaccines that a country can apply for in a single application round. However, only one vaccine per country will be funded per application round as determined by the prioritisation mechanism (please see section 2.9 for further information on prioritisation). Also countries can apply for support for partial introduction or for a phased rollout of the introduction.

Auto-disable (AD) syringes for injection and reconstitution and safety boxes will be funded by GAVI and 'bundled' with vaccines sent to the countries. In no case will GAVI support replace government funds, thus support will not be provided for a vaccine that is already being purchased with government funds.

All countries are required to co-finance GAVI-supported vaccines, except for measles second dose and preventative campaigns for Yellow fever and Men A (See section 3).

GAVI NVS support may be requested for the duration of the cMYP that is aligned with national planning and budgeting processes. Also GAVI will only review applications that propose an introduction date within 2 years of the application round (e.g. June 2013)

2.2 The Vaccine Introduction Grant

When approved for new and underused vaccine support for routine immunization⁷, countries will also receive a one-time cash grant to support additional costs related to new vaccine introduction and to fund pre-introduction activities.

What is it?

The vaccine introduction grant is expected to contribute to training, public information and social mobilisation⁸, cold chain improvements, vaccine delivery enhancements, printing and purchase of materials (such as immunisation cards), surveillance, and any other activities associated with the introduction of a new vaccine. The vaccine introduction grant cannot be used for vaccine co-financing or purchase of any vaccine.

When and how is it provided?

The vaccine introduction grant will be calculated as \$ 0.30 per infant in the birth cohort of the year of vaccine introduction with a minimum award of \$100,000. Although the vaccine introduction grant is a one-time award upon approval for NVS, it will be provided for each vaccine approved for a country through the GAVI NVS window. However, no introduction grant is provided for a change of formulation of the same vaccine, e.g. from lyophilized to liquid or 2 dose Rota to 3 dose Rota vaccines.

⁷ This does NOT relate to approvals for support for preventive campaigns

⁸ Public information and social mobilisation should be based on a thorough analysis of the gender and social barriers to access to immunisation and the actors that need to be targeted

What are the pre-requisites to obtain the grant?

In order to obtain this grant, countries must define all the pre-introduction activities they plan to conduct, the budget detailing the full non-vaccines cost (in line with the national vaccine introduction plan) and activities for which the GAVI grant will be used. This plan can be used to seek resources from national authorities or other partners in the event that the GAVI NVS introduction grant is not sufficient for all requirements. The application form contains specific tables that must be completed in order to be awarded the vaccine introduction grant. The introduction grant is subject to GAVI's terms and conditions related to cash-based support.

Operational costs for campaigns

GAVI does not provide introduction grant for preventive campaigns because it provides funds to support operational costs. The funding of operational costs is split between GAVI and the country. The operational costs provided by GAVI will be calculated at \$0.30 per person in the target population. In order to obtain funding for operational costs, countries must define all the activities that they plan to conduct, the budget detailing the full non-vaccine cost and activities for which the GAVI grant will be used. This plan can be used to seek resources from national authorities or other partners to complement GAVI funds for the campaign operational costs. The application form contains specific tables that must be completed in order to be awarded the operational costs support. The operational costs support for the approved countries will be disbursed from GAVI through WHO and UNICEF.

2.3 Background Information for each New and Underused Vaccine

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

Yellow fever vaccine for routine use

WHO policy states that the yellow fever vaccine is appropriate for routine use in Africa and the Americas, according to regional recommendations. GAVI will therefore contribute to topping-up of existing government financial commitments for yellow fever vaccine, where it is already part of a routine immunisation programme, and where yellow fever coverage is lower than measles coverage.

If shortfalls occur in the availability of the yellow fever vaccine for routine use, vaccines will firstly be allocated to countries already engaged in routine yellow fever immunisation to ensure sustainability of established programmes; and secondly to those at risk of yellow fever that are planning immunisation.

Preventive campaigns with Yellow fever vaccines

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. Countries at risk can apply for GAVI support (list provided in Annex B). It is expected that countries will maintain a high routine coverage following the campaign by mobilising resources domestically and from external donors.

GAVI will provide US\$ 0.30 per capita for the target population of the campaign to cover operational costs (approximately 50% of the total cost). The support will be provided in cash through WHO and UNICEF. Countries are expected to meet the remaining half of the operational expenses for the campaign. No co-financing of the vaccine by the country is required for preventive Yellow fever campaigns.

If the demand exceeds available supply, support will be granted according to recommendations by the International Coordinating Group (ICG).

Those countries that are eligible for support for Yellow fever preventive campaigns and are interested in applying will need to contact WHO⁹ to understand the level of support that they are entitled to under the relevant Investment Case.

Preventive campaigns with Meningococcal conjugate vaccines

To reduce the risk of Meningococcal A Meningitis epidemics in the 22 most affected countries in Africa, a one time preventive campaign with Men A is recommended in the population aged from 1 to 29 years old. Please refer to Annex B to see countries that are eligible for Men A support. GAVI will fully fund the vaccine needs for the preventive campaigns. The campaigns should be followed by routine vaccination of the new birth cohort each year after availability of an appropriate vaccine (anticipated for 2013). GAVI will also provide funding support to routine vaccines but the countries will also need to contribute payments according to the co-financing policy.

GAVI will provide US\$ 0.30 per capita for the target population of the campaign to cover operational costs (approximately 50% of the total cost). The support will be provided in cash through WHO and UNICEF. The countries are expected to meet the remaining half of the operational expenses for the campaign. No co-financing of the vaccine by the country is required for preventive campaigns for Men A.

If the demand exceeds available supply, support will be granted according to the recommendation of the International Coordinating Group (ICG).

Those countries that are eligible for support for Men A preventive campaigns and are interested in applying will need to contact WHO¹⁰ to understand the level of support that they are entitled to under the relevant Investment Case.

Measles vaccine second dose for routine immunisation

GAVI will provide support for countries to introduce a second dose measles vaccination into their routine immunisation programme, if this is included in the country's cMYP and the country has a measles coverage >80%. Countries are not expected to co-finance measles second dose introduction, however, they are required to provide evidence of a recommendation by WHO for introduction in their country. 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 (equivalent to the cost of the measles vaccine doses and injection safety material), based on the UNICEF weighted average price (WAP) for a 10 dose Measles monovalent presentation, and including freight and insurance charges. Further information is provided on the UNICEF Supply Division website or through the National UNICEF office. A country can use the funds to contribute to the purchase of a second dose measles vaccine presentation of their choice, either monovalent or combined with other antigens.

It is anticipated that most countries will procure the measles vaccine through UNICEF, however countries can self-procure the vaccine directly from the manufacturer if the product is WHO pre-qualified, or from a domestic supplier provided the country's NRA has been certified by WHO and has licensed the respective vaccine.¹¹

Pentavalent, Pneumococcal and Rotavirus vaccines

Based on current scientific evidence and the recommendations of the WHO Strategic Advisory Group of Experts on Immunisation (SAGE), WHO considers vaccines against Hepatitis B, *Haemophilus influenzae* type b (*Hib*), *Streptococcus pneumoniae* and Rotavirus vaccines appropriate for global use.

⁹ For further information please contact William Perea Caro at pereaw@who.org

¹⁰ For further information please contact Carole Tevi-Benissan at tevibenissanc@who.int

¹¹ WHO procedures require the manufacturer meet WHO requirements and produce the vaccines under the regulatory supervision of an agency assessed by WHO and certified to meet WHO requirements for a National Regulatory Authority in a vaccine producing country

Only for the 2011 round, any country with DTP3 coverage above 50% (WHO-UNICEF estimates for 2009)¹² will be considered for any of these three new vaccines which protect against the diseases referred to above if these vaccines are not currently part of their routine immunisation programme and funded with government funds.

The following should be considered when applying for new vaccine support:

- 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 doses schedule.
- Pneumococcal vaccine (PCV):
 - Available in two formulations: a 10-valent vaccine in two-dose vial and a 13-valent vaccine in a single dose vial. Both formulations use a three-dose schedule.
 - For Pneumococcal vaccine support, countries are obliged to procure the vaccine solely through UNICEF Supply Division, due to the special funding and contracting requirements of the Advance Market Commitment.
- For Rotavirus vaccine:
 - Available in an oral monovalent vaccine in a two-dose schedule and an oral pentavalent vaccine in a three-dose schedule
- Support for the above vaccines is for routine infant immunisation according to WHO recommendations – primarily for children under one year of age. GAVI support is not available for a “catch up” campaign for these vaccines.
- As the requested vaccine presentation may be in limited supply or currently unavailable, countries should rank their preference in their application (e.g. - including a first, second option and third option, where appropriate). If a country does not indicate options, it will be assumed that they prefer to wait until the preferred product is available.
- Countries can make a request to change vaccine presentation in its Annual Progress Report and its approval will be subject to the recommendation of the Monitoring IRC and availability of the requested vaccine formulation.

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/immunization/topics/rotavirus/en/index.html>
- <http://www.who.int/nuvi/rotavirus/en/index.html>

Supply availability

The supplier base for all GAVI funded vaccines is currently limited but the supply landscape is constantly changing. Close coordination and management of supply and demand is required to ensure countries' needs can be met. For updates on supply availability, please consult the UNICEF Product Menu at¹³

http://www.unicef.org/supply/index_gavi.html

2.4 Effective Vaccine Management Assessment and Vaccine Storage

New vaccines are significantly more costly than traditional vaccines. Vaccine wastage needs therefore to be minimised through good planning and efficient vaccine management systems.

¹² http://www.childinfo.org/immunization_countryreports.html

¹³ For further information please contact Ann Ottosen at aottosen@unicef.org

WHO and partners have developed new tools to enable countries to better plan for good vaccine management, such as the Effective Vaccine Management Assessment Tool.

It is mandatory for a country applying for NVS to conduct an EVM assessment¹⁴ and an assessment of vaccine storage and transport capacities as managed by the country. The EVM and immunisation supply chain planning tools are available from WHO and UNICEF for guidance. These tools can also be accessed at http://www.who.int/immunization_delivery/systems_policy/logistics/en/index5.html.

Such assessments must have been conducted in the 36 months preceding the application date. An integral part of the EVM assessment is the Improvement Plan so the resulting Improvement Plan of the assessment must be included in the application documents. The Independent Review Committee will pay particular attention to the Improvement Plan derived from EVM or other assessment tools when reviewing new vaccine applications.

The Improvement Plan must also be reflected as an integral part of the country's cMYP. Countries are expected to report on progress of implementation of the Improvement Plan. The EVM results¹⁵ will remain valid for three years. This means that a country with an expired EVM or equivalent assessment will be required to attach to the Annual Progress Report the report and Improvement Plan of a new EVM assessment. The country can conduct such an assessment either on its own or seek assistance from partner organisations.

Immunisation supply chain planning for the introduction of a new vaccine must include the related additional storage and transport requirements.

2.5 Management Requirements

Planning for NVS support

GAVI seeks to increase countries' access to new and underused vaccines. However, the decision to introduce new vaccines has broad implications and many factors should be considered before applying for support. These include an assessment of the estimated burden of disease¹⁶, of the efficacy, safety and quality of the vaccine, its potential impact, of its contribution to achieving national goals and milestones, of alternative disease reduction strategies, vaccine presentations, additional vaccine/cold chain storage requirements, of the operational costs of delivering the new vaccine, and a financial analysis of the impact of new vaccine introduction in the national context where possible, as well as a statement on the intention to finance the sustained use of the vaccine. In absence of country information on burden of disease, a country can use regional data or information as appropriate.

The timing of the development and implementation of the cMYP should be aligned with the national health sector plan. If a cMYP is not available, or if the current national health sector plan does not include any of these elements, the ICC, Immunisation Programme team and National Health Planning Department should make every effort to undertake these analyses as part of the planning process before applying for support. Technical assistance to support this process is available through GAVI partners.

Applying for NVS support

Applying for NVS support requires a financial commitment also on the part of the government, so national authorities responsible for public finance and the preparation of health sector budgets should take an active role in the application process. In general, this will mean officials from the Ministry of Finance as well as the Ministry of Health will be involved in the process.

¹⁴ For 2011 applications GAVI will also accept VMA or EVSM assessments conducted in the last 36 months if the country has not yet conducted an EVM

¹⁵ Or equivalent

¹⁶ Please provide sex-disaggregated data if it is available

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, who must also endorse the application.¹⁷

Proposals for NVS should specify whether supplies (vaccines, injection materials) or a cash grant in lieu of supplies is requested¹⁸; how the supplies or funds will be transferred to and managed in country; how vaccine and injection safety supplies will be procured and managed; and how the Vaccine Introduction Grant will be used.

Procuring New and Underused Vaccines

With the exception of Pneumococcal vaccine, for the procurement of vaccines and associated injection safety supplies, countries can choose to receive either:

- The supplies in kind from GAVI (procured through UNICEF or PAHO's Revolving Fund), or
- Equivalent cash grant in lieu of supplies and procure directly with the vaccine producer.

It should be noted that under AMC requirements for PCV, countries must procure vaccines through UNICEF SD to benefit from AMC terms and conditions, including the co-financed portion.

In addition, countries may procure their co-financed portion through UNICEF or an alternative mechanism (to be specified in the application). Countries should plan their co-financing contributions and vaccine procurement in accordance with country planning and budget cycles, and clearly indicate the timing of these payments in the application. To ensure that vaccines will be procured from sources of assured quality, GAVI expects that most National Immunisation Programmes will use UNICEF to procure all vaccines and associated injection safety materials.

Procurement through UNICEF for the co-financed portion of vaccines and associated injection safety materials will be managed as a normal Procurement Services transaction. 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). Funds should not be transferred to GAVI.

If national authorities wish to use an alternative mechanism for procurement and delivery of supplies (financed by GAVI), the country is required to submit with their application the following:

- Description of other vaccines or immunisation commodities to be procured by the country and descriptions of the mechanism used.
- Assurance that vaccines will be procured from the WHO pre-qualified list of vaccines OR in the case of procurement of locally-produced vaccine, directly from the manufacturer provided that the vaccine has been licensed by the NRA and that the NRA has been certified by WHO. A list of WHO prequalified vaccines that can be filtered by vaccine type, manufacturer, and country of manufacturer can be found at http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html.

After the GAVI Board's approval of the proposal, GAVI will conduct a review of the procurement mechanism proposed by the country to assess if it satisfies GAVI's standards and to provide recommendations on minimum reporting requirements and improvements (if needed). The country will receive the total funding for the procurement in a lump-sum from GAVI only after it agrees to conform to GAVI's recommendations. This amount will be based on the equivalent value of the UNICEF weighted average price. If a country's negotiated price is higher than UNICEF's, the

¹⁷ Partners signing the proposal imply they have read it and been part of the process, but it implies no legal or financial commitment on part of their respective organizations.

¹⁸GAVI will not provide cash in lieu of supplies for pneumococcal vaccine support.

government must pay the difference in order to purchase enough vaccine to reach the target population. If the price is lower than UNICEF's, the country can retain the excess funds and should report how they were used in the immunisation programme in the Annual Progress Report.

Changes in presentation of a vaccine

After approval for support, a country may wish to change the original formulation and presentation of a vaccine containing the same antigen, (e.g. from lyophilised penta to liquid penta or to a different number of doses per vial). In such cases the introduction plan 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 health worker training plans. 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 the country, and availability of the vaccine requested and contracted.

Fragile countries

Countries in emergency situations (post-conflict or countries in special circumstances) may require partners, including CSOs, to take on extended roles in the preparation and implementation of country applications. In exceptional circumstances GAVI may consider proposals developed and signed primarily by development partners.

2.6 Monitoring of New Vaccine Support

GAVI prefers to rely on country systems for monitoring and auditing performance. National authorities will be required to monitor and report the number of children immunised and to monitor the allocation and use of funds to co-finance the vaccines and associated injection safety materials. Monitoring will be based on:

- Timely submission of the Annual Progress Reports which will include information on both achievements and forecasts (targets and co-payment)
- Data provided in the WHO/UNICEF Joint Reporting Form on Vaccine Preventable Diseases
- Reports on the management of vaccine stocks
- The procurement and delivery of supply in compliance with the co-financing agreement.

In addition, countries choosing to receive cash in lieu of supplies for the procurement and delivery of vaccines and associated injection safety supplies are required to:

- Report through the ICC on the number and value of doses self-procured, savings made, if any, and the delivery
- Record the national procurement principles and processes in the Annual Progress Report, to ensure that good procurement practices are followed (including integrity, competition, equal treatment, client service and adherence to the GAVI Vaccine Procurement Objectives)¹⁹
- Report on financial and procurement requirements agreed with GAVI

GAVI Annual Progress Reports

The receipt of satisfactory APRs is a condition for continuation of any form of GAVI support. The Government is responsible for submitting APRs annually, endorsed by the ICC to the GAVI Secretariat by 15 May. All APRs are reviewed by the Monitoring IRC. The APR should be submitted together with the minutes of the ICC meetings of the reporting year. The report should contain information on progress in implementation, coverage, co-financing commitments and payments.

¹⁹ 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 procurement process.

For the first year of support, an Inception Report should be submitted, reporting on progress during the first year against the baseline in the proposal, and outlining how the Vaccine Introduction Grant has been spent. Further guidelines on APRs are available on the GAVI website. Both the NVS application and APR are expected to be submitted electronically.

Changes in introduction plans and/or coverage

Significant changes in plans should be communicated to the GAVI Secretariat and UNICEF Supply Division, for those countries procuring through UNICEF. Changes may include accelerated or delayed introduction or increases or decreases in immunisation coverage.

Revised plans should be communicated through the APRs, however, urgent matters, especially those impacting on vaccine shipment quantities, should be brought to the attention of GAVI and UNICEF SD outside of the schedule of Annual Reports with endorsement of the ICC/NITAG.

Monitoring EVM improvement plan

Countries should pay particular attention to the implementation of the Improvement Plan as recommended by the EVM assessment. An EVM will remain valid for three years, after which it will need to be repeated. Countries should report on progress made in implementing the Improvement plan as part of the APR.

Monitoring vaccine stocks and wastage

Countries are expected to report on the availability of in-country vaccine stocks in the APR. In addition to this information, GAVI and UNICEF Supply Division may require this information prior to further shipments. 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 coverage or other reason. Two principles will be followed; reducing the possibility of vaccine wastage, and ensuring that there are no vaccine stock outs. Also, in the APR countries are expected to report on the country specific wastage rate of the vaccine that was introduced with GAVI support.

Financial reporting and Audit of GAVI Funds

Within one year of the close of the financial year, GAVI should receive external audit reports (e.g. Auditor General's Report or equivalent) of the account(s) holding the GAVI support in cash in lieu of supplies and procuring their own vaccines and related injection safety supplies. GAVI reserves the right to request an external audit of the accounts to be conducted at any time during or after the duration of the GAVI support. GAVI in-country partners, the government and the HSCC can communicate any concerns they might have about the use of funds to the GAVI Alliance Secretariat at any time.

Co-financing New and Underused Vaccines

3.1 Co-financing Overview

The objective of the co-financing policy is to put countries on a trajectory towards financial sustainability in order to prepare them for the phasing out of GAVI support for new vaccines, recognising that the time frame for attaining financial sustainability will vary across countries. The intermediate objective of the co-financing policy (for those countries with an extended time frame for achieving financial sustainability) is to enhance country ownership of vaccine financing. The co-financing requirements and commitments by the country should be included in the application to GAVI and in the corresponding comprehensive multi-year plan (cMYP).

There is a wide variability in countries' ability to co-finance new and underused vaccines. Therefore, GAVI-eligible countries are grouped into three categories, based on the latest GNI per capita (GAVI is currently using 2009 data). The full list of eligible countries and country groupings is given in Annex A. The table below provides the co-financing levels per dose for each country groupings. Co-financing levels for all vaccines are per dose except for Rotavirus vaccine²⁰.

Country Co-financing Groups

Group	GNI per capita threshold in 2010	Co-financing amount
Low-income	This group includes countries with GNI per capita at or below the World Bank low-income threshold (below \$995).	Co-financing obligation in 2012 and thereafter: \$0.20 per dose (no annual increase).
Intermediate	This group includes countries with GNI per capita above the World Bank low-income threshold but below the GAVI eligibility threshold (from \$995 to \$1,500).	Co-financing level in 2012: \$0.20 per dose. Thereafter, the dose amount would increase by 15% annually. When countries in the future transition from the low income to the intermediate group, they would start at \$0.20 per dose for vaccines, followed by 15% annual increases.
Graduating	This group includes countries with GNI per capita above the GAVI eligibility threshold, who are still receiving GAVI support (above \$1,500).	Co-financing level in 2012: Countries are expected to co-finance at 20% of the projected 2016 price. Thereafter, the dose amount would increase in a linear increase over a four-year period from the amount paid in 2012 to the projected price in 2017. Countries are required to fully finance the costs of vaccines and related injection safety equipment and freight costs by 2017.

All countries are expected to co-finance the vaccines at the minimum levels described above and higher contributions are encouraged to facilitate achievement of financial sustainability.

²⁰ For Rotavirus vaccine the levels are based on a two schedule for both presentations.

3.2 Co-financing Implementation

Timeline for implementation, grace period, and updates

These initial classifications were made according to the 2009 GNI per capita data, which were released by the World Bank in July 2010. Co-financing group thresholds will be updated annually by September each year according to the latest GNI per capita data, which is released by the World Bank in July. Countries will then be informed of any changes to their co-financing grouping and will have at least one year's notice to start co-financing according to their new country grouping.

The above co-financing groups and levels will be in effect from 1st of January 2012 until 2015. GAVI will review the co-financing policy in 2014 and this review will inform the groups and levels for the period post 2015.

Fulfilment of the co-financing commitment is defined by the country's purchase of the number of doses outlined 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 in the decision letter.

Default mechanism

A country enters into default when it has not fulfilled its co-financing commitment for a particular year by 31 December of that year.

If a country remains in default for more than one year, the GAVI Board may suspend support for the vaccine in question until the co-financing arrears are paid in full. There are exceptional circumstances that can prevent a country from fulfilling its co-financing commitments for example, severe natural, economic, social, or political difficulties. In these cases, the GAVI Board may grant a grace period or exemption. While in this grace period, GAVI will continue to finance GAVI-supported vaccines.

The following actions will be taken when countries enter into default status:

- Communication from the GAVI Secretariat on default status in January of the following year;
- Existing GAVI support (NVS, HSS, ISS) is continued;
- GAVI Secretariat and partners at regional and country levels work with the country to help it fulfill its co-financing commitment;
- New applications may be submitted but approval will be contingent upon a country coming out of default status;
- Information about the country's default status is posted on the GAVI website.

If a country remains in default for a longer time:

- More than one year: Support for the specific vaccine is suspended until the co-financing arrears are paid in full;
- Two years or more: All GAVI support is suspended until the co-financing arrears are paid in full.

4 Application Submission Procedures

4.1 Application Processes

An application for GAVI support should be completed by the Ministry of Health in close collaboration with the ICC. 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 cMYP. The Ministry of Finance should endorse all applications.

The latest guidelines and application form (available on GAVI's website) should be used and all applications and supporting documents should be submitted in electronic format in English, French, Spanish or Russian. Please ensure that the application is received by the GAVI Secretariat on or before the deadline. Proposals received after the deadline may not be reviewed.

Countries must submit a GAVI application form to apply for support; however countries are encouraged to make reference to the specific sections in the application form to submit additional supporting documents. To access the application form please go to www.gavialliance.org/

Approval procedures at GAVI

The application review process is conducted as follows:

- i. **Completeness check:** The applications received from countries are checked by the GAVI Secretariat for completeness and mandatory requirements. Incomplete or invalid proposals will not be reviewed by the IRC.
- ii. **Pre-assessment:** Applications are pre-assessed by WHO and UNICEF Supply Division with a particular focus on the validity of the information, consistency of data presented in the application, relevant technical details and the co-ordination with other sources of information.
- iii. **IRC review:** The IRC reviews the country proposals, taking into account the pre-assessment reports. Only those country proposals that are submitted to the GAVI Secretariat along with pre-assessment reports and other relevant information will be reviewed. The Committee reviews the proposals and gives its recommendations to the GAVI Alliance Board or Executive Committee.
- iv. **Endorsement:** The GAVI Alliance Board or Executive Committee approves the IRC recommendation
- v. **Confirmation:** A Decision Letter is sent to inform the country of the decision. UNICEF SD and other partners are also informed to facilitate preparatory activities, including vaccine shipments, for introduction of the vaccine in the country.

All efforts will be made by GAVI partners to provide countries with appropriate advice and support in case the IRC does not recommend the approval of their applications.

Possible IRC recommendations for application submissions include the following categories:

Application Outcomes	Explanation
Recommended for approval	The application meets all criteria and is approved for GAVI support.
Recommended for approval with clarification	The application lacks specific pieces of data, which must be provided generally within a month upon receipt of official decision letter. Data must be received before the application is considered officially approved for GAVI support.
Recommended for conditional approval	The application does not fulfil specific or significant 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, re-submission of a new application is required.
Recommended for resubmission	The application is incomplete and a full application should be submitted in a future round.

4.2 Prioritisation Procedure

In situations of insufficient funding, not all proposals recommended by the IRC will be approved for funding by the Board. In order to ensure that limited funds are transparently and objectively allocated to countries, GAVI has established a prioritisation procedure. Under this, country proposals will be ranked based on the following objectives: health impact, value for money, financial sustainability, and need – see table below. The mechanism creates an index that weights and aggregates indicators for each objective.

Of note, countries can apply for as many vaccines as they wish; however under the current financial circumstances only one application will be funded per country per round. All applications recommended for funding by the IRC will be ranked through the prioritization mechanism and then countries that have more than one application approved will be asked to choose only one. The proposals are submitted to the Board or Executive Committee, which decide how many applications can be funded in the light of GAVI's available funds. Any applications recommended by the IRC that are unfunded will be automatically included in the next round. These applications will not require additional review by the IRC, but will be subject again to prioritisation. If a proposal remains unfunded for two consecutive rounds, the country will have to reapply.

Overview of Prioritisation Mechanism objectives, criteria and indicators for NVS proposals:

Objective	Criteria	Indicator	Data source	Weight
Health Impact	Deaths averted per 1000 vaccinated	Country-and disease-specific death rate x vaccine efficacy x coverage	WHO (disease burden); WHO/UNICEF (coverage); Weekly Epidemiological Records, WHO and technical consensus (efficacy)	30%
Value for Money (Cost effectiveness)	Cost per death averted	Vaccine price x doses/deaths averted (calculated as in health impact formula)	GAVI Secretariat price projections; Health impact indicator	30%
Financial Sustainability	Government commitment to health	General government expenditure on health as percentage of total government expenditure	National Health Accounts (published by WHO)	25%
Need	Country income	GNI per capita (US\$, Atlas method)	World Bank	15%

5 Instructions for completing the GAVI application form

The application form for GAVI New and Underused Vaccine support can be found at: <http://www.gavialliance.org/support/how/guidelines/index.php>

5.1 Executive Summary

To be completed for all proposals. Please outline a synopsis of the proposal, including:

- The specific requests for support from GAVI, including:
 - The duration of support
 - The total amount of funds requested
 - Details of the vaccine(s) requested (if any)
- Relevant baseline data, including:
 - DTP3 and Measles coverage data (as reported on the WHO/UNICEF Joint Reporting Form)
 - Birth cohort, targets for immunisation coverage by vaccines
- Country preparedness
 - Summary of EVM assessment
- The nature of stakeholders participation in developing this proposal
 - Inter-Agency Coordinating Committee

5.2 Signatures of the Government and National Coordinating Bodies

The Minister of Health and the Minister of Finance or their delegated authority should sign all applications for GAVI support. Members of the Inter-Agency Coordinating Committee for Immunisation (ICC) should also sign the application form for any window of GAVI support. The signatures of ICC members on the proposal are considered to represent their agreement with the information and plans provided in the proposal, as well as their support for the implementation of the plans. It does not imply any financial or legal commitment on the part of the partner agency or individual. Please include the name, job title and contact details of the most appropriate person for GAVI to contact if there are queries about the application.

5.3 The Inter-agency Co-ordinating Committee for Immunisation and NITAG

All proposals should include:

- Minutes of the three most recent ICC/NITAG meetings (including the meeting where the new support was proposed and discussed and the meeting where the proposal was agreed)
- An ICC workplan for the forthcoming 12 months

The rest of the section should only be completed by countries that have not been approved for any kind of GAVI support within the last 12 months. 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, including the following factors:

- Terms of reference that incorporate all aspects of immunisation services and include the co-ordination and integration of all immunisation initiatives (including polio eradication, measles control, neonatal tetanus elimination);
- Frequency of meetings;
- Minutes of the meetings and how they are circulated to members;
- The level of the ICC chairperson within the Ministry of Health;
- The list of members;
- ICC work plan and plans and budget requirements for strengthening the ICC if necessary.

5.4 Immunisation Programme Data

This section should only be completed by countries that have not been approved for any kind of GAVI support within the last 12 months. The information should be taken from the comprehensive Multi-Year Plan for Immunisation (cMYP), and other relevant health sector and immunisation planning, budgeting and reporting documents (as available).

The cMYP consolidates existing plans into a single document that addresses global, national and sub-national immunisation objectives and strategies, and evaluates the costs and financing of that plan. The cMYP should fit within national planning processes and health sector planning and be synchronised with the national planning cycle.

The cMYP is based on a situational analysis conducted by the National Immunisation Programme and partners, which allows the setting of priorities, development of strategies and identified key activities and timelines, and an estimation of the current and future costs of the Programme.

Please insert into the appropriate table the most recent data for population, GNI per capita, number of infants surviving the first 12 months of life, infant mortality rate, percentage of GDP allocated to health, and percentage of government expenditure on health. Please also provide the additional information requested about the planning and budgeting context in the country.

This section should be completed by all countries that have not been approved for any kind of GAVI support within the last 12 months. Countries should include their cMYP with the application, as well as completing this section.

Using the information contained in the cMYP, all applications for GAVI support need to present:

- The current vaccination schedule of the immunisation programme
- The trends of immunisation coverage and reported cases of vaccine preventable diseases
- Baseline information including coverage and target data (and annual DTP drop out rates)
- Current and future costs for the programme (for the period of the cMYP)
- Projected sources of funding from all sources for the same period

New and underused vaccines support (NVS)

The plan for the introduction of each new and underused vaccine, as part of the national immunisation plan or cMYP, should include:

- A summary of the cMYP referring to the introduction of new and underused vaccines
- An EVM (or equivalent) assessment report and improvement plan, including 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
- How financial sustainability and co-financing will be achieved (for the cMYP and beyond)
- Burden of relevant diseases (based on reported cases or appropriate models), using the cMYP data (if available)
- Lessons learned from the introduction of previous new and underused vaccines in country; actions taken in response to recommendations made after an earlier post-introduction evaluation (PIE) (if applicable)
- List of the vaccines (and presentations) to be introduced with support from GAVI
- Using the tables on vaccine request (and the cMYP), data for the first preference vaccine on the:
 - Portion of supply to be procured by the country
 - Portion of supply to be procured by GAVI

Information on the cold chain capacity must be provided. As the first preference of vaccine may be in limited supply or currently not available, an alternative vaccine presentation should be identified in the application.

The application should provide detailed information on how the procurement and management of the new and underused vaccine will operate, including information on:

- How the NVS support will operate and be managed including procurement of vaccines (if a mechanism other than UNICEF for procurement and delivery of supply is proposed)
- How the vaccine introduction will be managed (refer to cMYP);
- How any funds should be transferred to the country by GAVI (if applicable);
- How the co-financing amounts will be paid (and who is responsible for this);
- How vaccine coverage will be monitored and reported.

Additional comments / recommendations from the Inter-Agency Coordinating Committee for Immunisation and other Health Sector Development Partners

If the Inter-Agency Coordinating Committee members, or any other health sector development partners (members of the national coordinating body, IHP committee) have any additional comments or recommendations on the country application for support, please include them here.

Banking Form

Please complete the “Banking Form” (Annex 1 of the application form) with the proposal for New and Underused Vaccine Support applications, in case you have not yet already done so for other types of support from GAVI, to enable receipt of the Introduction Grant.

GAVI Alliance Terms and Conditions

Countries will be expected to sign and agree to the outlined GAVI Alliance terms and conditions in the application form.

Annex A: GNI per Capita and Co-financing Country Groupings (for NVS Support)

2009 GNI PER CAPITA Ranked by 2009 GNI per capita (US dollars)

Country	2009 GNI per capita	Country	2009 GNI per capita
As Published by the World Bank on July 1st 2010			
Azerbaijan	4,850	Bangladesh	590
Angola	3,490	Burkina Faso	510
Armenia	3,100	Guinea-Bissau	510
Ukraine	2,800	Tanzania	500
Georgia	2,530	Rwanda	460
Timor Leste	2,460	Uganda	460
Indonesia	2,230	Central African Republic	450
Bhutan	2,020	Gambia, The	440
Sri Lanka	1,990	Mozambique	440
Kiribati	1,890	Nepal	440
Congo, Republic of	1,830	Togo	440
Honduras	1,820	Guinea	370
Bolivia	1,630	Madagascar	420
Moldova	1,590	Afghanistan	370
Mongolia	1,590	Niger	340
Djibouti	1,280	Sierra Leone	340
Sudan	1,230	Ethiopia	330
Papua New Guinea	1,180	Eritrea	300
Cameroon	1,170	Malawi	280
India	1,170	Congo, Democratic Republic	160
Nigeria	1,140	Liberia	160
Sao Tome and Principe	1,140	Burundi	150
Uzbekistan	1,100		
Cote d'Ivoire	1,060	Cuba ¹	NA
Yemen, Rep.	1,060	Haiti ¹	NA
Senegal	1,040	Myanmar ¹	NA
Lesotho	1,020	Somalia ¹	NA
Pakistan	1,020	Zimbabwe ¹	NA
Nicaragua	1,010		
Vietnam	1,010		
Zambia	970		
Mauritania	960	¹ Estimates are available in ranges only	
Solomon Islands	920	Cuba: Middle Income Country (\$3,946-\$12,195)	
Lao PDR	880	Haiti, Myanmar, Somalia and Zimbabwe:	
Comoros	870	Low Income Country (\$995 or less)	
Kyrgyz Republic	870		
Kenya	770		
Benin	750		
Ghana	700		
Tajikistan	700		
Mali	680		
Cambodia	650		
Chad	620		

The following table shows the country groupings according to the different levels of co-financing contributions.

Groupings	GNI per capita Threshold in 2010	Countries	Amount
Low Income Countries	<\$995	Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, CAR, Chad, Comoros, Congo DR, Eritrea, Ethiopia, Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Korea D.R., Kyrgyz Republic, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Lao PDR, Liberia, Rwanda, Sierra Leone, Somalia, Solomon Islands, Tajikistan, Tanzania, Togo, Uganda, Zambia and Zimbabwe	20¢ per dose and fixed
Intermediate Countries	>\$995 to <\$1,500	Cameroon, Cote d'Ivoire, Djibouti, Guyana, Nicaragua, Nigeria, Lesotho, Pakistan, Papua New Guinea, Sao Tome and Principe, Senegal, Sudan, Uzbekistan, Vietnam and Yemen	Starts at 20¢ per dose and increases 15% annually
Graduating Countries	>\$1,500	Angola, Armenia, Azerbaijan, Bhutan, Bolivia, Congo Rep., Cuba, Georgia, Honduras, Indonesia, Kiribati, Moldova, Mongolia, Sri Lanka, Timor-Leste and Ukraine	Starts at 20% of projected price and increases each year in linear ramp-up to projected price

Annex B: Country groupings according to type of support

GAVI eligible countries for Meningococcal preventive campaign and routine support

Country
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 (9 states)
Nigeria remaining states
Rwanda
Senegal
Sudan
Tanzania
Togo
Uganda

List of GAVI-eligible countries for Yellow fever preventive campaigns support

Country
Côte d'Ivoire
Ghana
Nigeria

Annex C: GAVI Alliance Terms and Conditions

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 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.

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.