



GAVI/13/202/MK/RK

The Minister of Health and Population
Ministry of Health and Population
Ramshah Path
Teku, Kathmandu 2063
Nepal

11 April 2013

Dear Minister,

Nepal's Proposal to the GAVI Alliance

I am writing in relation to Nepal's proposal to the GAVI Alliance for New Vaccines Support for **Pneumococcal vaccines and Measles-Rubella vaccine introduction grant**, which was submitted to the GAVI Secretariat in August 2012.

I am pleased to inform you that following the recommendation of the Independent Review Committee (IRC), Nepal has been approved by the DCEO on 27th March 2013 for GAVI support as indicated in the Appendices to this letter

The country will co-finance the procurement of Pneumococcal vaccine in accordance with the GAVI co-financing policy, and the terms and conditions of this letter and its Appendices.

Pneumococcal vaccine supply: In your GAVI application form, Nepal requested an August 2014 introduction date. However, please note that due to an unprecedented demand for the vaccines and the lead time required by manufacturers to increase vaccine production, the global supply of the pneumococcal vaccine will not meet all country requirements in the short term. As a consequence, the vaccine introduction timeframe may differ from that requested in your proposal. We expect to send you an update on the status of supply in the third quarter of 2013. Please note that once the timing of supplies is confirmed and an introduction date is agreed, a Decision Letter will be issued with the number of doses to be funded by GAVI, as well as the co-financing amounts.

For your information, this document contains the following important attachments:

Appendix A: Description of approved GAVI support to Nepal

Appendix B: Financial and programmatic information for Measles-Rubella Vaccine Introduction Grant

Appendix C: A summary of the IRC Report

Appendix D: The terms and conditions of GAVI Alliance support

GAVI Alliance sent a new Partnership Framework Agreement (PFA) designed to improve the ease and efficiency for countries to understand the GAVI requirements, all in one clear and standardised document, for ease of reference, the PFA includes appendices in the same format as Appendix B. GAVI will be in contact with you shortly in relation to this transition to the PFA with detailed supporting information.

The following table summarises the outcome for each type of GAVI support applicable to Nepal:

| New Vaccines Support <i>Type of vaccine</i> | Approved for the first year | Approved for the second year |
|---|------------------------------------|-------------------------------------|
| Measles Rubella Vaccine Introduction Grant | US\$ 554,500 | |

Please do not hesitate to contact my colleague Raj Kumar - rajkumar@gavialliance.org if you have any questions or concerns.

Yours sincerely,



Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
The Director of Medical Services
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank

Description of GAVI support to Nepal (the “Country”)

New Vaccines Support (NVS) - Measles-Rubella Vaccine Introduction Grant

The GAVI Alliance has approved the Country’s request as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines governing Nepal’s proposal application; and
- The final proposal as approved by the IRC, including any subsequent clarifications.

The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisation provided with these vaccines.

Item number 11 of Appendix B summarises the details of the approved GAVI support for vaccines in 2013.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies cannot be paid for using GAVI funding.

GAVI is not responsible for any liability that may arise in connection with the distribution or use of vaccines and related supplies after title to such vaccines and related supplies has passed to the country, excluding liability for any defect in vaccines and related supplies, which remain the responsibility of the applicable manufacturer.

GAVI support will only be provided if the Country complies with the following requirements:

Transparency and Accountability Policy(TAP): Compliance with any TAP requirements pursuant to the GAVI TAP Policy and the requirements under any Aide Memoire concluded between GAVI and the country.

Financial Statements & External Audits: Compliance with the then-current GAVI requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with GAVI’s standard grant terms and conditions (attached in Appendix D).

Monitoring and Annual Progress Reports: Nepal’s use of financial support for the introduction of new vaccinations with Measles-Rubella vaccines is subject to strict performance monitoring. The GAVI Alliance uses country systems for monitoring and auditing performance as well as other data sources including WHO/UNICEF immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and the delivery of funds to co-finance the vaccine.

Nepal will report on the achievements and request support for the following year in the Annual Progress Report (APR). The APR must contain information on the number of children reported to have been vaccinated with DTP3 and 3 doses of pentavalent vaccine by age 12

months, based on district monthly reports reviewed by the ICC, and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May every year. Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports and availability of funds.

Measles-Rubella VACCINE SUPPORT

This Decision Letter sets out the Programme Terms of a Programme.

| | | | | | |
|---|-------------|-------------|-------------|-------------|--------------------------|
| 1. Country: Nepal | | | | | |
| 2. Grant Number: 13-NPL-98e-Y | | | | | |
| 3. Decision Letter no: 1 | | | | | |
| 4. Date of the Partnership Framework Agreement: N/A | | | | | |
| 5. Programme Title: New Vaccine Support | | | | | |
| 6. Vaccine type: Measles-Rubella | | | | | |
| 7. Requested product presentation and formulation of vaccine: N/A | | | | | |
| 8. Programme Duration¹: 2013 | | | | | |
| 9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement) | | | | | |
| | 2013 | 2014 | 2015 | 2016 | Total² |
| Programme Budget (US\$) | N/A | N/A | N/A | N/A | N/A |
| 10. Vaccine Introduction Grant: US\$ 554,500 payable up to 6 months before the introduction. | | | | | |
| 11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):³ | | | | | |
| Type of supplies to be purchased with GAVI funds in each year | 2013 | | | | |
| Number of Measles-Rubella vaccines doses | N/A | | | | |
| Number of AD syringes | N/A | | | | |
| Number of re-constitution syringes | N/A | | | | |
| Number of safety boxes | N/A | | | | |
| Annual Amounts (US\$) | N/A | | | | |
| 12. Procurement agency: Not applicable | | | | | |
| 13. Self-procurement: Not applicable. | | | | | |

¹ This is the entire duration of the programme.

² This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.

³ This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently. *Ceci est le montant approuvé par GAVI. Prière de modifier les montants annuels indicatifs des années précédentes si cela change ultérieurement*

| | |
|--|-------------|
| 14. Co-financing obligations: Not applicable | |
| 15. Operational support for campaigns: Not applicable | |
| | 2013 |
| Grant amount (US\$) | N/A |
| 16. Additional documents to be delivered for future disbursements: Not applicable | |
| Reports, documents and other deliverables | Due dates |
| N/A | N/A |
| 17. Clarifications: Not applicable | |
| 18. Other conditions: Not applicable. | |

Signed by

On behalf of the GAVI Alliance

Hind Khatib-Othman

Managing Director, Country Programmes

11 April 2013

IRC NVS Country Report

Country: Nepal

Type of support requested: NVS

Vaccines requested: Pneumococcal (PCV 13)

Measles Rubella Vaccine Introduction Grant

Reviewed:

Geneva, 8th – 19th October 2012

Country profile/Basic data (2011)

| | | | |
|-----------------------------------|--------------------|------------------------------|------------|
| Population (NDHS) | 28,480,314 | Infant mortality rate (2011) | 46/1000 LB |
| Birth cohort (JRF) | 655,777 | Govt. Health expenditure | 6 % |
| Surviving infants (JRF) (HMIS) | 655,777 659,016 | GNI/capita (2011) | US\$ 540 |
| DTP3 coverage (administrative) | 92 % | Co-financing country group* | Low |

*low income, intermediate or graduating

1. Type of support requested/Total funding/Implementation period

- Single dose PCV (13-valent) for the period 2014-2016. The total amount of funds requested from GAVI is US\$ 24,305,000. The GoN will co-finance US\$ 1,364,500.
- Vaccine introduction grant for introduction of MR vaccine into routine immunization.

2. History of GAVI support

Table 1. NVS and INS Support

| NVS and INS support | Approval Period |
|---------------------|-----------------|
| Hep B mono | 2002-2004 |
| DTP-Hep B | 2005-2015 |
| Pentavalent | 2009-2015 |
| INS | 2002-2005 |

Table 2. Cash Support

| Cash support | Approval Period |
|--------------|-----------------|
| ISS | 2002-2011 |
| HSS | 2008-2013 |

3. Composition & Functioning of the ICC

According to meeting minutes, the Inter Agency Coordinating Committee comprises members from the Ministry of Health, Rotary International, Lions Club, UNICEF, USAID, WHO Sabin Institute and Nepal Red Cross. In their deliberations, issues discussed were the MR catch-up campaign and submission of the GAVI new vaccine introduction proposal.

A NITAG group was formed in 2009 as a stand-alone committee, which meets twice a year, and whose membership includes the Ministry of Health, an epidemiologist, pediatricians, Paediatric Association, Department of Drug Administration, WHO and UNICEF. This committee provides technical guidance to the MoH and the National Program of Immunisation on immunization and technical resources to assist government in evidence-based decision making, as well as being the technical arm that supports the country's stewardship immunization program.

4. Status of the National Immunisation Programme

The immunization program in Nepal has made notable achievements, with a DTP3 coverage above 80% sustained over the last five years and an increase to 92% in 2011. Specific survey results indicate a 92% coverage for DTP3, 90% coverage for measles and 96% for BCG. The JRF country official estimates and WHO/UNICEF estimates are consistent. The country projects that they shall reach 95% of the children with both DTP3 and PCV3; this is within reasonable projections.

Gender and Equity

Gender has not been addressed as part of the application. The proposal mentions that gender will be addressed through social mobilization, IEC and advocacy, but there is no mention of it when discussing IEC in the introduction plan. It is mentioned that coverage for all antigens in the highest wealth quintile is 95% and 85% in lowest wealth quintile. Coverage also increases with the education of mothers, 92% among children of mothers with higher education and 78% for children of mothers with no education. It is also stated that urban children are more likely to get vaccinated (90%) than rural children (88%).

There is no significant difference in immunization for all antigens between boys and girls. There is currently a national health information system pilot in 15 districts that is providing disaggregated data by sex, caste and ethnicity.

5. Comprehensive Multi Year Plan (cMYP) overview

The duration of the current cMYP is 2011-2016. While the country has been in the process of conducting an MR campaign in a phased approach, and based on the measles elimination objective, the country wishes to take advantage of the MR vaccine and introduce it into the routine immunization program. The introduction of new and underused vaccines (rubella, pneumococcal, typhoid, rotavirus) would be based on disease burden and financial sustainability in the country and expansion of cold chain capacity at all levels.

The cMYP has provided an appropriate situation analysis of the immunization. Some problems requiring special strategies were identified: include hard to reach areas; inadequate ownership by local governments; urban slums also hard to reach; national immunization section of the CHD department understaffed in comparison with the increased demand for work to be anticipated with the introduction of new vaccines (only 1 NIP National Manager and 2 technical staff); and inadequate monitoring of vaccine wastage.

In addition to this, the reasons for not fully immunized children identified through the 2009 survey were: unaware of need for immunization (48%); fear of side effects (44%); no faith in immunization (36%); wrong ideas about contraindications (25%); mother/guardian too busy (23%); and place of immunization too far (34%). However, solutions to all the identified problems are not well stipulated.

6. New vaccine introduction plan

Pneumococcal (PCV 13)

Assessments of invasive bacterial disease have been conducted, and 2011 data from the one sentinel site indicated very low number of positive cases. This has been attributed to the very wide use of antibiotics prior to the clinical investigation. On the other hand, 2008 estimates for pneumococcal disease are higher, with around 1,398 cases nationwide, while pneumococcal meningitis deaths are estimated at 106 annually.

The GoN proposes that US\$ 550,615 of the required US\$ 678,409 funds from GAVI be allocated as follows: training; cold chain equipment and maintenance; mobilization of municipal authorities; and surveillance and monitoring. Strategies outlined to reduce vaccine wastage are as follows: refresher trainings on vaccine management to all EPI staff; analysis of vaccine stocks, updating/strengthening of the logistics management information to receive accurate and timely up-to-date information status of stocks of vaccines and cold chain equipment; monitoring of vaccine wastage at all levels; implementation of the multi-dose vial policy; and measuring immunization performance including vaccine wastage.

Vaccine introduction grant for introduction of MR vaccine into routine immunization

Following the completion of the campaign, Nepal plans to replace the measles vaccine at 9 months with the MR vaccine in routine immunization. The scheduled introduction of MR vaccine into the routine immunization program is April 2013.

Analysis of rubella cases reported through measles surveillance, 2004 - 2009; in 2008, rubella seroprevalence among women 15 to 39 years of age was evaluated; and also in 2009, children attending a school for the deaf were examined for ocular defects associated with CRS. More than 95% of the 3,710 confirmed rubella cases were less than 15 years of age. Of 2,224 women of child bearing age (WCBA) tested for anti-rubella IgG, 2,020 (90.8%) were seropositive. It was estimated that approximately 1,426 infants were born with CRS (192/100,000 live births) in 2008. Among 243 students attending a school for the deaf, 18 (7.4%) met the clinical criteria for CRS. US\$ 554,116 from the GAVI introduction grant will be used to fund training, cold chain and maintenance, vehicles and transportation and program management as the main activities.

AEFI

An AEFI surveillance system is in place in all 75 districts and staff is trained. An independent AEFI committee has been formed at national level and all serious AEFI cases are investigated by AEFI committee members.

7. Improvement plan

An EVM was conducted in December 2011. The service point level has a very low rating on criteria E5 (Maintenance) and E6 (Stock management), whereas primary level rated low in criteria E2 (Storage Capacity). This insufficient storage capacity at the primary level has been rectified with the installation of a walk in cold room.

The status of implementation of the recommendations was tabulated and significant progress at each level of the cold chain system was accomplished. However, there are still a number of recommendations on cold chain and logistics that need follow up, such as provision and use of freeze indicators during transport of freeze-sensitive vaccines at all levels. The next EVM assessment is planned for January 2014.

8. Cold chain capacity

Nepal has one national cold room, six regional cold rooms and 75 district cold rooms. The available vaccine storage capacity at the National level in 2010 was 40,096 liters. An estimate of the vaccine storage capacity was conducted and it was revealed that, from 2012 to 2014, the capacity at the national vaccine store is sufficient to accommodate routine EPI, PCV and MR vaccines. However, with the introduction of more vaccines, such as Rota and HPV, vaccine storage capacity will be insufficient.

Vaccine storage capacity at the district and health facility level could not be determined without the inventory record. However, the country has a plan to update the inventory of all cold chain equipment from central to district level by 2012. Procurement of sufficient cold boxes and vaccine carriers at each level was done to handle the shortage. Other recommendations on cold chain and logistics were already initiated and implementation is in progress.

9. Financial Analysis

Pneumococcal (PCV 13)

The total cost of vaccine and injection supplies being requested from GAVI for PCV13 (2014-2016) is US\$ 24,305,000 (according to Table Annex 1.1 B in the proposal) while the country's co-financing amounts to US\$ 1,364,500.

According to the Application Form (AF), the total budget for the PCV13 introduction is US\$ 678,140, and the country asks GAVI to finance 81% of the budget (US\$ 550,616). Almost two thirds of the total budget are allocated to training (35%) and cold chain equipment (34%).

The introduction plan did not provide additional information on the introduction plan budget or on the financial implications of PCV13 on the EPI.

MR introduction grant

According to the AF, the total cost of MR introduction is estimated at US\$ 768,021, out of which 72% are requested to be financed by GAVI (US\$ 554,116). Training and cold chain equipment absorb up to two thirds of the budget (43% and 22%, respectively). It is not specified how the remaining 28% will be financed.

The country estimated the funding gap to be 21% of the total immunization resource requirements for 2011-2015 (US\$ 25.4 million) in the cMYP (2011/12-2015/16). It should be noted that the cMYP covers financial projections for 2011-2015 only and it appears not to have been updated. Therefore, the introduction plan and cMYP did not fully cover the new vaccine introduction period with financial projections and analysis.

10. Co-financing arrangements

The country proposes to co-finance each dose of PCV13 with US\$ 0.2, which corresponds to the minimum required level for countries in the low income group. The country used the old version of the cMYP costing tool in which there is no separate column for planned financing of co-financing portion of the vaccines. Neither the introduction plan nor the cMYP support the following statement of the country in the AF "The Ministry of Health & Population, GoN will pay the co-financing amounts to UNICEF as per MoU."

11. Consistency across proposal documents

Generally, there is consistency across documents regarding the timeframe, but there are some differences in population figures. The monitoring IRC report on Nepal indicates that denominators would be adjusted following the release of the 2011 census in the country. The value of the request differs significantly in the cMYP as compared to those in the application, including the co-financing. The country's immunization coverage estimates are consistent with those of WHO/UNICEF. The Government's commitment in supporting the MR catch up campaign prior to introducing MR into the routine service is impressive.

12. Overview of the proposal: Strengths & weaknesses

Strengths: The application for support of introduction of PCV and MR into the immunization schedule is based on evidence of local disease burden. Introduction plans are available for both PCV and MR. Co-financing for the PCV is committed by the government, as is the commitment to self-procure MR after introduction. Cold chain is reported to be adequate for the introduction of both vaccines into the routine schedule.

Weaknesses: Some programmatic aspects of which the program seems to be aware, although well described in the analytical part of the cMYP, are not well addressed in the implementation section. They include issues like understaffing at central level of the EPI section under CHD, no strategies for hard to reach urban areas and no proper wastage monitoring. No financial analysis in the cMYP on sustainability.

It is unclear whether the pool funding will be used as per SWAP arrangement of several donors/partners as described in the cMYP. The lack of information on the inventory of cold chain equipment at service delivery/health facility level weakens the proposal.

The report indicates that GAVI finances 72% of MR introduction and does not specify the other sources of financing of the remaining 28%. Financial implications of the introduction of new vaccines (including funding gap analysis and feasible financial sustainability strategies) are not explicitly presented or discussed. Funding of co-financing obligations (for PCV13) are not reflected in the financial projections

Mitigating factors: For future introductions, the country would benefit from reviewing the EVM reports and updating the improvement plan, as well as updating the cMYP costing tool to reflect more accurate costing for the program. If the pool funding of the SWAP coordination does not come through, the planned activities might be jeopardized in terms of insufficient co-financing.

13. Recommendations

Vaccine: Pneumococcal (PCV 13)
Recommendation: Approval

Support: Measles Rubella Vaccine Introduction Grant
Recommendation: Approval

14. Other comments

Note to the GAVI Secretariat: GAVI Secretariat to inform the country and follow up accordingly, ensuring that weaknesses and concerns highlighted by the IRC (above) are taken into consideration and that this is reviewed by next year's Monitoring IRC.

Note to the Monitoring IRC: IRC to pay particular attention to the extent to which the country considered the weaknesses highlighted above and revised core documents accordingly.

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.