

Application Form for Gavi NVS support

Submitted by

The Government of Lesotho

Date of submission: 15 January 2016

Deadline for submission:

i. 15 January 2016

ii. 1st May 2015

iii. 9 September 2015

Select Start and End Year of your Comprehensive Multi-Year Plan (cMYP)

Start Year

2012

End Year

2017

Form revised in 2015

(To be used with Guidelines of November 2015)

Note: Please ensure that the application has been received by Gavi on or before the day of the deadline.

Gavi GRANT TERMS AND CONDITIONS

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

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

AMENDMENT TO THE APPLICATION

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

RETURN OF FUNDS

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

SUSPENSION/ TERMINATION

The Gavi 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 the Country's application, or any Gavi-approved amendment to the application. The Gavi retains the right to terminate its support to the Country for the programmes described in its application if a misuse of Gavi funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the Gavi shall not be offered by the Country to any third person, nor will the Country seek in connection with its 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, as requested. The Gavi 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 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 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 in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, and Annual Progress Report, are accurate and correct and form legally binding obligations on the Country, under the Country's law, to perform the programmes described in its application, as amended, if applicable, in the APR.

CONFIRMATION OF COMPLIANCE WITH THE GavI TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the Gavi Transparency and Accountability Policy (TAP) and complies with the requirements therein.

USE OF COMMERCIAL BANK ACCOUNTS

The Country is responsible for undertaking the necessary due diligence on all commercial banks used to manage Gavi cash-based support. The Country confirms that it will take all responsibility for replenishing Gavi cash support lost due to bank insolvency, fraud or any other unforeseen event.

ARBITRATION

Any dispute between the Country and the Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the Gavi 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 languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the Gavi. 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 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 will not be liable to the country for any claim or loss relating to the programmes described in the 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 its application.

1. Type of Support requested

Please specify for which type of Gavi support you would like to apply to.

Type of Support	pe of Support Vaccine		End Year	Preferred second presentation[1]
Preventive Campaign Support	MR, 10 dose(s) per vial, LYOPHILISED	2016	2017	

[1] Gavi may not be in a position to accommodate all countries first product preferences, and in such cases, Gavi will contact the country and partners to explore alternative options. A country will not be obliged to accept its second or third preference, however Gavi will engage with the country to fully explore a variety of factors (such as implications on introduction timing, cold chain capacity, disease burden, etc.) which may have an implication for the most suitable selection of vaccine. If a country does not indicate a second or third preference, it will be assumed that the country prefers to postpone introduction until the first preference is available. It should be noted that this may delay the introduction in the country.

2. Table of Contents

- 1. Type of Support requested
- 2. Table of Contents
- 3. Executive Summary
- 4. Signatures
 - 4.1. Signatures of the Government and National Coordinating Bodies
 - 4.1.1. Government and the Inter-Agency Coordinating Committee for Immunisation
 - 4.1.2. National Coordinating Body Inter-Agency Coordinating Committee for Immunisation
 - 4.1.3. Signature Table for the Coordinating Committee for Immunisation
 - 4.2. National Immunization Technical Advisory Group (NITAG)
 - 4.2.1. The NITAG
- 5. Immunisation Programme Data
 - 5.1 Background information
 - 5.1.1 Lessons learned
 - 5.1.2 Health planning and budgeting
 - 5.1.3 Gender and equity
 - 5.1.4 Data quality
 - 5.1.6 MCV Immunisation coverage
 - 5.2. Baseline and Annual Targets (NVS Routine Support)
 - 5.3. Targets for Preventive Campaign(s)
 - 5.3.1 Targets (MR campaign)
- 6. New and Under-Used Vaccines (NVS Routine)
- 7. NVS Preventive Campaigns
 - 7.1. Assessment of burden of relevant diseases related to campaigns (if available)
 - 7.1.1 Epidemiology and disease burden for Measles-Rubella
 - 7.2 Request for MR, 10 dose(s) per vial, LYOPHILISED campaign support
 - 7.2.1 Summary for MR campaign support
 - 7.2.2 Grant Support for Operational Costs of the MR Campaign
 - 7.2.3 Evidence of introduction of MR in routine programme
 - 7.2.4 Introduction planning for RCV
 - 7.2.5 Rubella Containing Vaccine introduction Grant
- 8. Procurement and Management
 - 8.1 Procurement and Management of New and Under-Used Vaccines Routine
 - 8.2 Procurement and Management for NVS Preventive Campaign(s)
 - 8.2.1 Procurement and Management for MR, 10 dose(s) per vial, LYOPHILISED campaign
 - 8.3 Product Licensure
 - 8.4 Vaccine Management (EVSM/EVM/VMA)
 - 8.5 Waste management

9. Additional Comments and Recommendations from the National Coordinating Body (ICC/HSCC)

10. List of documents attached to this proposal

11. Annexes

Annex 1 - NVS Routine Support

Annex 2 - NVS Routine - Preferred Second Presentation

Annex 3 - NVS Preventive campaign(s)

Table Annex 3.1 C Summary table for vaccine MR, 10 dose(s) per vial, LYOPHILISED

<u>Table Annex 3.1 D Estimated numbers for MR, 10 dose(s) per vial, LYOPHILISED, associated injection safety material and related co-financing budget</u>

Annex 4

Table Annex 4A: Commodities Cost

Table Annex 4B: Freight cost as percentage of value

<u>Table Annex 4C: Preparing transition phase - Minimum country co-payment per dose of co-financed vaccine</u>

Table Annex 4D: Wastage rates and factors

Table Annex 4E: Vaccine maximum packed volumes

12. Banking Form

3. Executive Summary

Please provide a summary of your country's proposal, including the following the information:

- For each specific request, NVS routine support or NVS campaign :
 - The duration of support
 - The total amount of funds requested
 - Details of the vaccine(s), if applicable, including the reason for the choice of presentation
 - Projected month and year of introduction of the vaccine (including for campaigns and routine)
- Relevant baseline data, including:
 - DTP3 and Measles coverage data (as reported on the WHO/UNICEF Joint Reporting Form)
 - Target population from Risk Assessments from Yellow Fever and Meningitis A
 - Birth cohort, targets and immunisation coverage by vaccines
- Country preparedness
 - Summary of planned activities to prepare for vaccine launch, including EVM assessments, progress on EVM improvement plans, communication plans, etc.
 - Summary of EVM assessment and progress on EVM improvement plan
- The nature of stakeholders' participation in developing this proposal
 - Inter-Agency Coordinating Committee
 - o Partners, including CSO involvement

Lesotho seeks GAVI support towards the introduction of the combined measles-rubella (MR) vaccine into the country's routine immunization programme. MR vaccine will be introduced for both the first and second doses of the measles-containing vaccine (MCV). GAVI is being requested to support the planned introduction through the Vaccine Introduction Grant (VIG), the MR Introduction budget totals to \$100,000. The introduction will be done through a catch up campaign targeting children aged 9 months to 14 years which is intended to accelerate population immunity scheduled for October 2016. The budget for the campaign totals to \$563, 190. The campaign is planned to last 10 days following which, the MR Vaccine will form part of the national routine immunization schedule.

Lesotho has a birth cohort of 54,772[1]. All children are eligible to receive immunization services regardless of geographic location, socio-economic status or gender. WHO-UNICEF estimates state the DPT3 coverage to be at 96% and the MCV coverage to be at 92%[2]. After the 2009-2010 measles outbreak in southern Africa, resulting in 2,488 reported cases in Lesotho in 2010, suspected measles cases decreased to 172, 179, and 516 in 2011, 2012, and 2013, respectively.

According to measles case based surveillance, no measles IgM positive cases have been reported in 2014 and 2015. Between 2002 and 2009, 428 rubella cases were documented in Lesotho. The total annual number of rubella IgM-positive cases reported by the country, 2011-2014 was 82, 166, 244, 294 and 129, respectively, indicating continued rubella transmission in the country. More than half (47.3%) of all febrile rash cases investigated in 2015 were due to Rubella.

The planned MR introduction comes at a time when Lesotho's health system is being strengthened following past assessments including the EVMA in December 2014. The Ministry of Health and partners have drawn an EVM Improvement plan and are in the implementation stage. Continuous temperature monitoring devices have been introduced in fridges at all levels of the supply chain and a temperature mapping exercise completed at the national vaccine store. MOH has also completed a comprehensive Cold Chain Inventory and drawn a cold chain expansion and improvement plan. The country will utilize HSS funds to procure recommended equipment and increase capacity at all levels and address gaps identified by the CCI. In the coming months, there are plans to develop standard operating procedures (SOP's) and build capacity of health workers on stock and vaccine management and distribution.

The MR Introduction plan was developed collaboratively with representatives from the Ministry of Health's Expanded Program on Immunization (EPI), support from partners WHO, UNICEF and Clinton Health Access Initiative (CHAI) and has been endorsed by Lesotho's Inter-Agency Coordinating Committee.

[1] 2014 Lesotho Demographic & Health Survey

[2] http://www.gavi.org/country/lesotho/

4. Signatures

4.1. Signatures of the Government and National Coordinating Bodies

4.1.1. Government and the Inter-Agency Coordinating Committee for Immunisation

The Government of Lesotho would like to expand the existing partnership with the Gavi for the improvement of the infants routine immunisation programme of the country, and specifically hereby requests Gavi support for:

MR, 10 dose(s) per vial, LYOPHILISED preventive campaigns

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

Please note that this application will not be reviewed or recommended for approval by the Independent Review Committee (IRC) without the signatures of both the Minister of Health and Minister of Finance or their delegated authority. These signatures are attached as DOCUMENT NUMBER: 2 and 1 in Section 10. Attachments.

Ministe	r of Health (or delegated authority)	Minister of Finance (or delegated authority)		
Name HON. DR 'MOLOTSI MONYAMANE		Name	HON. DR MAMPHONO KHAKETLA	
Date		Date		
Signature		Signature		

This report has been compiled by (these persons may be contacted in case the Gavi Secretariat has queries on this document):

Full name	Position	Telephone	Email
Ms Lineo Mathule	UNICEF, EPI Focal Point	+266 22315801	Imathule@unicef.org
Ms Selloane Maepe	WHO, EPI Officer	+266 22312122	maepes@who.int

4.1.2. National Coordinating Body - Inter-Agency Coordinating Committee for Immunisation

Agencies and partners (including development partners and NGOs) supporting immunisation services are coordinated and organised through an inter-agency coordinating mechanism (ICC, Health Sector Coordinating Committee (HSCC), or equivalent committee). The ICC, HSCC, or equivalent committee is responsible for coordinating and guiding the use of the Gavi NVS routine support and/or campaign support. Please provide information about the ICC, HSCC, or equivalent committee in your country in the table below.

Profile of the ICC, HSCC, or equivalent committee

Name of the committee	Lesotho ICC		
Year of constitution of the current committee	1996		
Organisational structure (e.g., sub-committee, stand-alone)	Stand alone		
Frequency of meetings	Quarterly and or when there is need		

The Terms of Reference or Standard Operating Principles for the ICC, including details on the ICC membership, quorum, dispute resolution process and meeting schedules is attached as DOCUMENT NUMBER: 4.

Major functions and responsibilities of the ICC/HSCC:

Major functions of the ICC include the following:

1. Coordination:

The ICC coordinates partners with view of fostering strong partnership which which facilitates planning resources and sharing of technical inputs. This ultimately will lead to effective utilization of available resources

2. Advocacy:

The committee lobby on behalf of the programme at the higher administrative and political levels in the country and internationally to improve programme performance

3. Resource Mobilization:

It is the responsibility of ICC to review and endorse National EPI programme plans, mobilize resources for the programme both locally and internationally

4. Transparency and accountability:

Since ICC is responsible for mobilizing resources for EPI, the committee is obliged to review and monitor use of such funds and other resources together with EPU unit, provides feedback to donors and other relevant stakeholders as need arise.

5. Advisory role:

ICC has to play an advisory role to the Ministry of Health in matters that affect and pertain to National EPI programme

6.Monitoring and Evaluation:

The ICC is further responsible for ensuring periodic programme reviews, monitoring through quarterly meetings and timely sharing of EPi reports with relevant authorities both locally and internationally. Also ensures operationalisation of technical guidelines for better achievement of programme standard indicators

7. Social Mobilization:

One of the critical tasks of ICC is to support communication on immunizations and vaccines to ensure wider publicity of the programme

Please describe how partners have provided support in preparation of the proposal:

In-country meetings were held with technical support from WHO and UNICEF to prepare all relevant materials needed to compile this application. Further in country technical support was obtained from WHO sub-regional office and incountry partners such as UNICEF and CHAI supported the Ministry to develop MRCV This application. Further support was sought to update cold chain planning tool and national EPI vaccine and logistics forecasting tool to facilitate assessment of future needs of the country in terms of storage capacity for both vaccines and vaccine supplies at national and district stores including the cost of vaccines. Preparation of this proposal was guided through the use of materials which were made available for reference purposes.

4.1.3. Signature Table for the Coordinating Committee for Immunisation

We the members of the ICC, HSCC, or equivalent committee [1] met on the 10/12/2015 to review this proposal. At that meeting we endorsed this proposal on the basis of the supporting documentation which is attached. The minutes of the meeting endorsing this proposal are attached as Document number 5. The signatures endorsing the proposal are attached as Document number 7 (please use the list for signatures in the section below).

Please refer to Annex C of the 'Gavi HSS and NVS General Guidelines' for more information on ICCs.

Function	Title / Organisation	Name	Please sign below to indicate the attendance at the meeting where the proposal was endorsed	to indicate the
----------	----------------------	------	--	-----------------

			proposal was discussed
Chair	MINISTER OF HEALTH, LESOTHO	DR 'MOLOTSI MONYAMANE	
Secretary	MINISTRY OF HEALTH, LESOTHO	MALEKHETHO MOTENALAPI	
Members	Refer to attachment	Signatures endorsing the application	

By submitting the proposal we confirm that the quorum has been met. Yes

The minutes from the three most recent ICC meetings are attached as DOCUMENT NUMBER: 6.

4.2. National Immunization Technical Advisory Group (NITAG)

Has a NITAG been established in the country? No

In the absence of a NITAG, countries should clarify the role and functioning of the advisory group and describe plans to establish a NITAG. This document is attached as **(Document Number: 8)**

5. Immunisation Programme Data

5.1 Background information

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

- Please refer to the Comprehensive Multi-Year Plan for Immunisation (cMYP) (or equivalent plan) and attach a complete copy (with an Executive Summary) as DOCUMENT NUMBER 9. Please attach the cMYP costing tool as DOCUMENT NUMBER 10.
- Please attach relevant Vaccine Introduction Plan(s) as DOCUMENT NUMBER: 12
- Please refer to the two most recent annual WHO/UNICEF Joint Reporting Forms (JRF) on Vaccine Preventable Diseases
- Please refer to Health Sector Strategy documents, budgetary documents, and other reports, surveys etc, as appropriate.
- Please refer to the attached risk assessments in the case of yellow fever and meningitis A mass preventive campaigns.

Please use the most recent data available and specify the source and date.

	Figure	Year	Source
Total population	1,954,906	2015	BoS
Birth cohort	54,877	2015	BoS
Infant mortality rate (per 1000)	59	2014	2014, LHDS
Surviving infants[1]	52,195	2015	BoS
GNI per capita (US\$)	1,350	2014	World bank,/GAVI NVS guidelines
Total Health Expenditure (THE) as a percentage of GDP	14	2014	Ministry of Health 2014 Annual Joint Review
General government expenditure on health (GGHE) as % of General government expenditure	12	2010	World Health Report

[3] Surviving infants = Infants surviving the first 12 months of life

5.1.1 Lessons learned

Routine New Vaccines Support

Preventive campaign support

If campaigns with MR vaccines have already been conducted in your country, please give details of the lessons learned, specifically for: storage capacity, protection from additional freezing, staff training, cold chain, logistics, coverage, wastage rate, etc., and suggest action points to address them in future campaigns. If they are included in the Introduction Plan or Plan of Action, please cite the section only. If this information is already included in NVIP/POA, please reference the document and in which section/page this information can be found.

Lessons Learned	Action Points
Campaigns for MR vaccines have not been conducted. However, measles campaigns have been previously conducted and these are the lessons learned: 1. The capacity building in health facility and district microplanning can be replicated to strengthen routine	Implementation of RED/REC approach should be optimally utilized in Lesotho. community structures should be involoved in the health facility microplanning
immunization Early preparation is the key to successful implementation of	Implementation of campaign plan of action should start six months
the campaign	prior to the campaign

Detailed logistic plan, early and appropriate social mobilization activities contributed to the success of the campaign	There is need to designate a specific person to focus on logistics and both national and district level to ensure adequate and timely distribution of supplies to the periphery
Effective planning, coordination and presence of a full time consultant made implementation more efficient	Need to have a consultant in country at least three months before the campaign
Strong partnership is essential for the success of the campaign	Early involvement of partners in the early planning stages of the campaign should be initiated early
	Involve community councils in the planning and social mobilization to ensure ownership in the implementation of the camapign

5.1.2 Health planning and budgeting

Please provide information on the planning and budgeting cycle in your country

The Government of Lesotho (GoL) budget cycle runs from April to March of the following year. Relevant planning document is health sector policy framework which derives directly from broad government objectives outlined in the country Vision 2020 Document, 2012-2017 National Health sector Policy and the 2012-2017 National Health strtategic Plan (NHSP).

Please indicate the name and date of the relevant planning document for health

National Health Sector Policy 2012-2017

Is the cMYP (or updated Multi-Year Plan) aligned with the proposal document (timing, content, etc.)

The cMYP has been updated and is aligned with national health goals as outlined in the National Health Strategic Plan (NHSP) and expands on the immunizations as indicated in the maternal and child health cluster of the NHSP in terms of timing and content. Overall, the cMYP articulates the immunization goals to be achieved in order to effectively contribute to the attainment of national global and goals, in particular, MDG4 for child survival.

Please indicate the national planning budgeting cycle for health

1st April to 31st March the following year

Please indicate the national planning cycle for immunisation

1st April to 31st March the following year

5.1.3 Gender and equity

Please describe any barriers to access, utilisation and delivery of immunisation services at district level (or equivalent) that are related to geographic, socio-economic and/or gender equity. Please describe actions taken to mitigate these barriers and highlight where these issues are addressed in the vaccine introduction plan(s).

In Lesotho, all children are eligible to receive free immunization services regardless of geographic location, socio-economic status or gender. The 2014 LDHS estimates that the vaccine coverage rate for all basic vaccinations is equal for males and females at 68.3%. Similarly, vaccination rates are not significantly higher in urban areas than in rural areas at 70.1% and 67.6% respectively (2014 LDHS). There is some range in the vaccination rates of infants according to wealth with those in the middle quintile receiving the highest rate of vaccine coverage at 81.5% and those in the bottom quintile receiving the lowest at 59.7%, surprisingly those in the highest quintile have nearly the mean vaccination coverage at 68.4% (2014 LDHS). As a marker of geographic equity, only two of ten districts have a DTP3 coverage rate below 80%. However, given the potential for topography as a barrier to vaccination access Lesotho, MoH has put in place a number of measures to ensure that services are provided to the community. These include the Lesotho Flying Doctor Service, which provides support to remote facilities, and HSS funds that are being utilized to address support

systems for areas that may be at risk of becoming bottlenecks to vaccine delivery services, such as transport and funds to support health worker facilitation of community outreach.

Discuss how equity issues (geographic, socio-economic and/or gender) are being taken into account in the design of social mobilisation and other strategies to increase immunisation coverage. Highlight where these issues are addressed in the vaccine introduction plan(s).

All children are eligible to receive immunizations irrespective of geographic location. However, the terrain of the country becomes a barrier to provision of immunization services, especially during rainy seasons when rivers are in flood and during winter whereby snowfalls are experienced. In that regard, existing community structures such as village health workers, local chiefs, community counsels, church leaders and other community workers have been instrumental in supporting social mobilization activities. Availability of communication networks plays an important role. This becomes more visible during implementation of supplementary immunization activities. Therefore, with introduction of rotavirus, the plan is to develop health facility and district microplans to ensure that hard -to-reach communities are mapped in terms of number of children residing there, which will facilitate the assessment of appropriate resources and strategies to be employed to reach them on quarterly basis.

Please indicate if sex disaggregated data is collected and used in immunisation routine reporting systems.

In Lesotho, sex-disaggregated vaccination data is routinely collected and reported into the DHIS2 HMIS system. Gender-disaggregated data is also collected during the 5-yearly DHS. There are no documented gender barriers to immunization and the basic vaccination coverage rate is equal for boys at girls at 68.3% (2014 LDHS). Moreover, country EPI policy clearly states that immunization services should be offered to all eligible children regardless of gender. Similarly, health education sessions held during ANC visits emphasize the importance of providing immunizations to all children. Furthermore, any other communication and social mobilization activities and messages are delivered in such a way that parents of boy and girl children get equal opportunities to receive immunization services. Similarly, gender of health care providers does not affect delivery of immunization services.

Is the country currently in a situation of fragility (e.g. insecurity, conflict, post-conflict, refugees/and or displaced persons and recent, current or potential environmental disaster, such as flooding, earthquake or drought or others)? If Yes, please describe how these issues may impact your immunisation programme, planning for introduction of routine vaccines or campaigns and financing of these activities.

Lesotho is not in the situation instability, but the country is going through drought disaster which has been declared as an emergency. This may cause efforts aimed at supporting immunization programme to be diverted to emergency relieving activities

If available, please provide additional information and documents on subnational coverage data, e.g. comparing urban/rural districts or districts with highest/lowest coverage, etc.

The LDHS 2014 provided an opportunity for validation of routine immunization administrative data. Coverage for individual antigens is estimated to be high, with 80% districts achieving DTP3 coverage above 80% and 20% districts achieving between 60 and 80% (LDHS 2014). Coverage ranges cannot be explained by difference in urban and rural services as vaccination rates are not significantly higher in urban areas than in rural areas at 70.1% and 67.6% respectively (2014 LDHS). While there is some disparity in vaccination coverage among Lesotho's 10 districts (ranging from 47.5% to 79.5%), overall the immunization coverage of children across different demographic factors still shows limited correlation either gender, topographical or wealth disparities.

In Lesotho, national household surveys that are routinely carried out are the EPI cluster survey, last conducted in 2013, which included the post measles SIA evaluation, as well as the Lesotho Demographic and Health Survey last conducted in 2014. The EPI cluster survey did not assess immunizations based on gender, instead it considered in terms of difficult terrain. The 2014 LDHS, on the other hand, assessed gender related provision of vaccinations and reported same coverage for basic vaccination (68.3%) for both males and females, which indicates that all children in Lesotho have equal opportunities to immunizations. In relation to equity, two household surveys showed higher coverage in the urban than rural areas mainly due to ease of access to services in urban than rural. Activities to assess equity related barriers are not included this

application as the Rotavirus vaccine will be integrated into the routine country household surveys nor has there historically been concerns around gender equity barriers.

5.1.4 Data quality

Please attach a data quality assessment (DQA), report if one has been completed within the previous 48 months (DOCUMENT NUMBER: 27). If available, an improvement plan and progress report on the implementation of the improvement plan should also be submitted (DOCUMENT NUMBER: 11, DOCUMENT NUMBER: 28).

If DQA not available, please briefly describe plans to establish mechanisms for data quality assessment.

Data quality has been documented as a challenge in Lesotho on several occasions: Gavi DQA of 2008, Data Quality Self -assessment of 2012, EPI cluster survey conducted in 2013 and comprehensive EPI review of 2014. Therefore the country is planning to embark on the following priorities to address data quality issues:

- Develop and implement data quality improvement plan
- Reinforce use of village health registers to complement the use of under five clinic registers
- Strengthen defaulter tracking efforts
- Encourage head count of all children under the age of five to determine target population for health centers
- Revitalize the use of District Vaccination Data Management Tool (DVDMT)
- Ensure that there has been adequate training on data collecting, recording, and use throughout the pre-introduction phase, as well as including a post introduction assessment of data quality

Please indicate what routine mechanisms to independently assess the quality of administrative data are in place, and if so what these mechanisms are and how they enable the country to track changes in data quality over time.

There are two routine household surveys that are used as mechanisms to independently assess the quality of administrative data: the EPI cluster survey, last in 2013, and the 2014 LDHS. Results from these surveys inform and guide the M&E unit of the Ministry of Health, as well as the programme, to put in place efforts to improve the quality of admin data. The Annual Joint Review process includes data validation through visits to a sample of facilities to review routine data, including immunization data. At the facility level, health center committees assist with head counts for catchment population verification.

Please detail what household surveys have been conducted in recent years to independently assess immunisation coverage and equity, and describe any survey plans for the coming five year period.

The demographic and health survey (DHS) conducted in 2014 provided opportunity for routine administrative data to be validated. The country conducted an EPI cluster survey at end 2013 and hopes to conduct the next one post 2016 campaign evaluation following the planned MR SIAs in 2016. The next DHS will take place in 2019.

5.1.5 MCV Immunisation coverage

Please provide information concerning immunisation coverage related to measles-containing vaccines (MCV)

Table 5.1.5: MCV Immunisation coverage

Coverage	2011		2012		2013	
Coverage	Administrative(1)	WUENIC(2)	Administrative(1)	WUENIC(2)	Administrative(1)	WUENIC(2)
Measles 1 <i>st</i> dose (%)	61	92	60	92	60	92
Measles 2 <i>nd</i> dose (%)	0	82	0	82	0	82

Coverage	20	14	2015		
Coverage	Administrative(1)	WUENIC(2)	Administrative(1)	WUENIC(2)	
Measles 1 <i>st</i> dose (%)	58	92		0	
Measles 2 <i>nd</i> dose (%)	0	82	0	0	

Coverage	20	11	20	12	20	13
Coverage	Administrative(1)	Coverage survey	Administrative(1)	Coverage survey	Administrative(1)	Coverage survey
Supplementary Immunisation Activities (SIA) (%)	0	0	0	0	72.2	78.8

Coverage	20	14	2015	
Coverage	Administrative(1)	Coverage survey	Administrative(1)	Coverage survey
Supplementary Immunisation Activities (SIA) (%)	0	0	0	0

Note:

- (1) National reported Administrative Coverage
- (2) WHO/UNICEF estimates of national immunization coverage

Was the last Measles Supplementary Immunization Activities (SIA) administrative coverage or results of a survey of acceptable methodology Results of a survey

Please describe survey methodology:

Cluster sampling technique was applied in accordance with WHO immunization cluster survey. Clusters were selected based on the statistical parameters and clusters were randomly selected at national level with assistance from Lesotho BoS.

5.2. Baseline and Annual Targets (NVS Routine Support)

No NVS Routine Support is requested

5.3. Targets for Preventive Campaign(s)

5.3.1 Targets (MR campaign)

Please specify cohort for rubella-containing vaccines (RCV):

MR Start 9 months

MR End 14 years

Cohort population = population 9 months - 14 years old

Gavi will only provide support to countries for Rubella Containing Vaccine catch-up campaign by providing doses of MR vaccine for a target population of males and females aged 9 months to 14 years (the exact range in the scope of 9 months to 14 years old will depend on MR in the country).

Table 5.3.1 Baseline NVS preventive campaign figures for MR

Ni mahan	Targets		
Number	2016	2017	
Total target population	871,822	51,664	
Wastage rate (%) for MR (campaign)	25	25	
Maximum wastage rate value for MR (campaign)	0 %	0 %	

6. New and Under-Used Vaccines (NVS Routine)

No NVS Routine Support is requested

7. NVS Preventive Campaigns

7.1. Assessment of burden of relevant diseases related to campaigns (if available)

Disease	Title of the assessment	Date	Results
Rubella	Measles case-based surveillance	2001-2015	Measles Elimination and Control The Lesotho measles elimination plan of action was developed in 1999 focusing on intensified routine immunization, social mobilization, surveillance and conducting National Immunization Days (NIDs). Measles Case Based Surveillance started in 2001 and this included rubella. No measles IgM positive cases have been reported in 2014 and 2015. Between 2011 and 2015, 915 rubella cases were documented in Lesotho. The total annual number of rubella IgM- positive cases reported by the country, 2011-2015 was 82, 166, 244, 294 and 129, respectively, indicating continued rubella transmission in the country. More than half (47.3%) of all febrile rash cases investigated in 2015 were due to Rubella. The country does is planning do retrospective record review to document the baseline which will be followed by by MR surveillance Age group of people who tested positive for rubella in 2015, range between 1 year and 16 years in 70% of districts.

Please attach the Plan of Action for each campaign as Document No. 29,23 in Section 10.

7.1.1 Epidemiology and disease burden for Measles-Rubella

Please select at least one of the following information sources to justify RCV diseases burden results: Epidemiological information on burden of disease:

- □ 1 Rubella data from the measles case-based surveillance system (including the age distribution of rubella cases)
 □ 2 Rubella seroprevalence surveys
 □ 3 Congenital Rubella Syndrome (CRS) burden information, e.g. retrospective search, modelled estimates for CRS burden, prospective surveillance
- □ 4 Other

7.2.Request for MR, 10 dose(s) per vial, LYOPHILISED campaign support

7.2.1. Summary for MR campaign support

When is the country planning to conduct the MR catchup campaign? October 2016

When is the country planning to introduce MR into routine immunisation? October 2016

Please note that, due to a variety of factors, the launch date may vary compared to the date stipulated in the application. Gavi will work closely with countries and their partners to address this issue.

Please give a summary of the cMYP and/or the MR, 10 dose(s) per vial, LYOPHILISED introduction plan sections that refer to the introduction of MR, 10 dose(s) per vial, LYOPHILISED. Outline the key points that informed the decision-making process (data considered etc) and describe the plans for social mobilisation and microplanning, including strategies for insecure or hard-to-reach areas. If they are included in the introduction plan or plan of action, please cite the sections only.

Introduction of MR is included in the narrative cMYP section:1.5.4 under vaccines and logistics.

Key points that informed decision making are increasing numbers of suspected measles cased that tested positive for rubella from 2011-2014:No measles IgM positive cases have been reported in 2014 and 2015. Between 2011 and 2015, 915 rubella cases were documented in Lesotho. The total annual number of rubella IgM-positive cases reported by the country, 2011-2015 was 82, 166, 244, 294 and 129, respectively, indicating continued rubella transmission in the country. More than half (47.3%) of all febrile rash cases investigated in 2015 were due to Rubella. Furthermore, technical support and provision of position papers on rubella further strengthened decision by the country to introduce MR. Evidence from previous campaigns report, indicated that more children could be reached through outreach than static sites. Therefore, efforts will be put in place to ensure early preparation and proper microplanning. Social mobilization is key to successful introduction and implementation of campaigns, use of existing community structures such as community counsellors, local chiefs, church leaders and village health workers will form part of the preparations and implementation of the capmaign.

Please summarise the cold chain capacity (at central and other levels) and readiness to accommodate new vaccines, taking into consideration training, cold chain **equipment** and other **logistical** requirements. If cold chain expansion is required, state how it will be financed, and when it will be in place. Please describe how the surge capacity for campaigns will be managed. Please indicate if the supplies for the campaign will have any impact in the shipment plans for your routine vaccines and how it will be handled. The Independent Review Committee requires assurance that the cold chain is ready or will be ready for the campaign, and evidence/plans need to be provided (if they are included in detail in the plan of action, please cite the section here). **All proposals** that include Gavi-financing for cold chain equipment intended for vaccine storage shall need to procure equipment pre-qualified by WHO under their Performance Quality and Safety (PQS) program. The purchase of non-PQS equipment will only be considered on an exceptional basis, with justification and advance agreement from Gavi. Please note that all Gavi-financed cold chain equipment needs to be WHO pre-qualified. The purchase of non-PQS equipment will only be considered on exceptional basis, with justification and advance agreement from Gavi.

please refer to section:1.13 on overview of cold chain capacity at central and district level.

Please describe how the campaign activities will contribute to strengthening routine immunisation services. Please refer to specific activities to be undertaken during planning and implementation, to evaluate the implementation of the routine strengthening activities completed during the campaign, and to assess, via an independent survey, the quality and coverage achieved through the campaign.

Campaign activities that will contribute to strengthening routine immunization will iclude:

Health worker training and development of microplans. Training will be done in a cascade manner where central level managers will ttrai district supervisors through Tots and this will be followed by training of lower level personnel. regarding logistics, care will be taken to ensure that hard to reach and under served like mountains, special means of transport is arranged. Precampain assessment will be undertaken to validate level of preparedness for the campaign at districts and health centre levels. Social mobilization activities shall be conducted and coordinated at district level while central level shall be responsible for development and printing of communication matereals. Local community structres will be oriented and will lisise with district coordinators to inform sites and dates for the campaign.

Phases of monitoring campaign will be in place: precampaign supervision, supervision during the campaign, intra-campaign supervision and independent campaign quality monitoring. Post campaign evaluation will be undertaken to validate administrative coverage. This will be combined with EPI cluster survey to ensure inclusion of other antigens.

Please describe any plans for expanding measles surveillance to include rubella and plans for the introduction of Congenital Rubella Syndrome (CRS) surveillance.

The country conducts measles case based surveillance which includes rubella. However, the plan is to conduct retrospective record reveiw which will be followed by CRS surveillance.

Please submit relevant documentation to support the estimates of the size of the campaign target population (as DOCUMENT NUMBER : 18).

7.2.2. Grant Support for Operational Costs of the MR Campaign

Table 7.2.2: calculation of grant to support the operational costs of the campaigns

Year of MR support	Total target population (from Table 5.3)	Gavi contribution per target person in US\$	Total in US\$
2016	871,822	0.65	566,684
2017	51,664	0.65	33,582

^[1] The Grant will be based on a maximum award of \$0.65 per target person

[2] Please add a line for each calendar year for SIAs being implemented over different years.

Please describe how the grant will be used to facilitate the preparation and timely and effective delivery of the campaigns to the target population (refer to the cMYP and the Vaccine Introduction Plan).

Gavi campaign grant will be used to support the following activities:

- Training of health workers and health promotion officers. This will include adaptation of WHO rotavirus materials and printing of the field guide and other materials. Training will then be conducted through cascaded trainings, starting with 36 national-level Training of Trainers, who will be Public Health Nurses drawn two from each of 18 district hospital health areas. These TOTs will then be responsible for training an average of 3 health workers from each facility in their catchment area, with more from large facilities, and fewer from smaller facilities. Government of Lesotho will cover part of the training costs, and the transportation costs of health workers for central training, There will also be one centralized training for health promotion officers, also funded by Government funds. Therefore, the VIG funding will cover printing of materials, and some of the costs of delivering facility-based trainings.
- Social mobilization, IEC, and advocacy. Vaccine introduction grant will support the costs of developing, pretesting, and printing IEC materials including posters and banners. These materials will then be used in trainings of Village Health Workers, Health Center Committees, and sensitization meetings with district leaders in each of the 10 administrative districts. There will be one central-level launch and 9 small-scale district launches. All of the social mobilization costs will be paid for with Gavi VIG funds.

Additional costs will be covered by government and by partners, as follows:

- **Programme Management** costs including supportive supervision will be covered by the Government of Lesotho, and surveillance costs will be covered by WHO.
- **Distribution costs** for the vaccine will be covered by the routine MOH budget, as the vaccine will be distributed together with the routine allocations to districts and to facilities.
- WHO will cover the cost of a Post-Introduction Evaluation.

A detailed budget is attached and included in the Introduction Plan.

Where Gavi support is not enough to cover the full needs, please describe other sources of funding and the expected amounts to be contributed, if available, to cover your full needs.

In the event that GAVI VIG funds are not sufficient to cover planned costs, resources will be mobilized from the government and in country health development partners including WHO, UNICEF, and CHAI to meet full operational needs.

Please complete also the 'Detailed budget for VIG / Operational costs' template provided by Gavi and attach as a mandatory document in the Attachment section.

Detailed budget attached as Document No. 22.

7.2.3 Evidence of introduction of MR in routine programme

Please provide evidence that the country can finance the introduction of Rubella-Containing-Vaccine (RCV) into the routine programme through one of the following:(Please attach available documents AS DOCUMENT NUMBER 17 in Section 10. Attachments)

- 1 A commercial contract for purchase of MR/MMR vaccine with or without shipping documents, invoice, etc.
- 2 Integration of RCV into the cMYP with a corresponding increase in the budget line for vaccines in the ☑ health sector budget adequate to cover purchase of RCV (please highlight the budget line in the cMYP costing or other document showing the corresponding increase to cover the purchase of RCV).
- 3 An MOU between government and donor(s) (or other written document) committing the donor(s) to support for at least one year, the purchase of RCV for use in the routine programme **OR** a letter from the Minister of Finance or Budget ensuring additional funding for RCV purchase. In this case, the country must show additional evidence that the country will include MR vaccination in the routine immediately after the

campaign.

7.2.4 Introduction planning for RCV

Countries should describe their plan for introduction including surveillance activities:

Does Lesotho's cMYP include a plan for the introduction of RCV into the national programme? Yes

Please attach the Introduction Plan for the introduction of RCV into the national programme as **Document number 13** in Section 10 and also attach the Plan of Action for the campaign as **Document number 29** in Section 10. Please refer to the Gavi application guidelines for required components in the introduction plan and plan of action.

GAVI application guidelines were used as reference while preparing introduction plan which will be attached.

7.2.5 Rubella Containing Vaccine introduction Grant

Has a Rubella Containing vaccine already been introduced nationally on a routine basis? No

Calculation of Vaccine Introduction Grant for the MR, 10 dose(s) per vial, LYOPHILISED

Please indicate in the tables below how the one-time Introduction Grant [1] will be used to support the costs of vaccine introduction and critical pre-introduction activities (refer to the cMYP). Gavi's support may not be enough to cover the full needs so please indicate in the table below how much and who will be complementing the funds needed.

Year of New Vaccine Introduction	Birth cohort (from Table 5.1)	Gavi contribution per target person in US\$	Total in US\$
2016	54,877	0.80	100,000

[1] The Grant will be based on a maximum award of \$0.80 per person in the birth cohort with a minimum starting grant award of \$100,000

Please describe how the Gavi Vaccine Introduction Grant will be used to facilitate the timely and effective implementation of critical activities in advance of and during the introduction of the new vaccine (refer to the cMYP and the Vaccine Introduction Plan).

Gavi vaccine introduction grant will be used to support the following activities:

• Training of health workers and health promotion officers. This will include adaptation of WHO rotavirus materials and printing of the field guide and other materials. Training will then be conducted through cascaded trainings, starting with 36 national-level Training of Trainers, who will be Public Health Nurses drawn two from each of 18 district hospital health areas. These TOTs will then be responsible for training an average of 3 health workers from each facility in their catchment area, with more from large facilities, and fewer from smaller facilities. Government of Lesotho will cover part of the training costs, and the transportation costs of health workers for central training, There will also be one centralized training for health promotion officers, also funded by Government funds. Therefore, the VIG funding will cover printing of

materials, and some of the costs of delivering facility-based trainings.

• Social mobilization, IEC, and advocacy. Vaccine introduction grant will support the costs of developing, pretesting, and printing IEC materials including posters and banners. These materials will then be used in trainings of Village Health Workers, Health Center Committees, and sensitization meetings with district leaders in each of the 10 administrative districts. There will be one central-level launch and 9 small-scale district launches. All of the social mobilization costs will be paid for with Gavi VIG funds.

Additional costs will be covered by government and by partners, as follows:

- **Programme Management** costs including supportive supervision will be covered by the Government of Lesotho, and surveillance costs will be covered by WHO.
- **Distribution costs** for the vaccine will be covered by the routine MOH budget, as the vaccine will be distributed together with the routine allocations to districts and to facilities.
- WHO will cover the cost of a Post-Introduction Evaluation.

A detailed budget is attached and included in the Introduction Plan.

8. Procurement and Management

8.1 Procurement and Management of New and Under-Used Vaccines Routine

No NVS Routine Support is requested

8.2 Procurement and Management for NVS Preventive Campaign(s)

8.2.1 Procurement and Management for MR, 10 dose(s) per vial, LYOPHILISED campaign

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

Lesotho procures all vaccines; traditional, new and under-used through UNICEF supply division. Therefore a similar arrangement will be followed for the MR vaccine

b) Please describe the financial management procedures that will be applied for the management of the preventive campaign cash support, including any procurement to be incurred.

A new vaccine breakdown budget will be developed to cost all pre-introduction activities to be undertaken. Overall management of NVS cash will be the responsibility of MoH. The funds will be directed to Central Bank of Lesotho where a foreign currency denominated account (FCDA) already exists to receive funds from Gavi. These funds will further be transferred to MoH to be managed through MoH Project Accounting Unit (PAU).

c) Please indicate if the campaign is going to be phased, and if so, how this will be done.

The campign will conducted nationwide at the same period.

d) Please outline how coverage of the campaign will be monitored, reported and evaluated (refer to the cMYP and/or the MR, 10 dose(s) per vial, LYOPHILISED campaign introduction plan)

Tools will be made available and campaign implementers trained on the use. Daily daily data harmonization and estimation coverage for each outreach site will be conducted. independent monitoring shall be instituted to ensure that all eligible children have been reached, where missed children are identified, teams shall be mandated to call back. At the end of the campaign, there will be end process rapid assessment survey (household) conducted to assess the quality of implementation, especially in high risk areas to identify poorly covered, missed areas so that they can be revisited.

8.3 Product Licensure

For each of the vaccine(s) requested, please state whether manufacturer registration and/or national vaccine licensure will be needed in addition to WHO prequalification and, if so, describe the procedure and its duration. In addition, state whether the country accepts the Expedited Procedure for national registration of WHO-prequalified vaccines.

Note that the necessary time for licensure should be factored into the introduction timeline and reflected in the Vaccine Introduction Plan or Plan of Action.

At present, there is no drug regulatory authority in Lesotho, however the Pharmaceuticals Directorate in the Ministry of Health oversees introduction of new products and product selection. Therefore the government relies on WHO prequalification status for new vaccines. Vaccines that are WHO prequalified and imported through UNICEF SD can be used in the population, but since the product has not been previously registered, a waiver will be required for each shipment. There is no challenge anticipated in obtaining this waiver.

For each of the vaccine(s) requested, please provide the actual licensure status of the preferred presentation and of any alternative presentations, if required.

WHO prequalified only

Please describe local customs regulations, requirements for pre-delivery inspection, special documentation requirements that may potentially cause delays in receiving the vaccine. If such delays are anticipated, explain what steps are planned to handle these.

Lesotho does not encounter delays related to customs, inspection or documentation

Please provide information on NRA in the country, including status (e.g. whether it is WHO-certified). Please include points of contact with phone numbers and e-mail addresses. UNICEF will support the process by communicating licensing requirements to the vaccine manufacturers where relevant.

Currently there is no drug regulatory authority in lesotho. However, the Ministry of Healtj is in the process of forming such authority. Currently ther is pahrmaco vigilance unit that regulate drugs in the country.

8.4 Vaccine Management (EVSM/EVM/VMA)

It is mandatory for countries to conduct an Effective Vaccine Management (EVM) assessment prior to an application for the introduction of a new vaccine. This EVM should have been conducted within the preceding **5 years**.

When was the EVM conducted? December 2014

Please attach the most recent EVM assessment report (DOCUMENT NUMBER: 20,19,21), the corresponding EVM improvement plan (DOCUMENT NUMBER: 19) and progress on the EVM improvement plan (DOCUMENT NUMBER: 21). The improvement plan should include a timeline, budget of committed resources for these activities and funding gaps, if any, as well as M&E indicators to monitor progress of implementation.

If any of the above mandatory documents (EVM Assessment Report, EVM Improvement Plan, Progress on the EVM Improvement Plan) are not available, please provide justification and reference to additional documents such as PIE and External EPI Reviews.

When is the next Effective Vaccine Management (EVM) Assessment planned? December 2017

EVM report, EVM im provement plan and progress on EVM improvement plan are attached to the application.

8.5 Waste management

Countries must have a detailed waste management and monitoring plan as appropriate for their immunisation activities. This should include details on sufficient availability of waste management supplies (including safety boxes), the safe handling, storage, transportation and disposal of immunisation waste, as part of a healthcare waste management strategy. Please describe the country's waste management plan for immunisation activities (including campaigns).

There is a waste management plan and EPI policy to guide safe handling, storage, transportation and disposal of waste. The country follows a three-bin system and sharps are deposited into a puncture resistant safety box provided in all health facilities, which offer immunization services. The main method of waste disposal is incineration and all safety boxes are collected from the health facilities and transported to the hospitals for incineration.

9. Additional Comments and Recommendations from the National Coordinating Body (ICC/HSCC)

Comments and Recommendations from the National Coordinating Body (ICC/HSCC)

10. List of documents attached to this proposal

10.1. List of documents attached to this proposal

Table 1: Checklist of mandatory attachments

Document Number	Document	Section	File		
Endorsements					
1	MoH Signature (or delegated authority) of Proposal	4.1.1	Minister's Signature.docx File desc: Date/time: 15/01/2016 11:42:20 Size: 12 KB		
2	MoF Signature (or delegated authority) of Proposal	4.1.1	Minister's Signature.docx File desc: Date/time: 15/01/2016 11:42:30 Size: 12 KB		
4	Terms of Reference for the ICC	4.1.2	ICC ToRs for ICC doc Jan 2016.pdf File desc: Date/time: 15/01/2016 10:59:32 Size: 245 KB		
5	Minutes of ICC/HSCC meeting endorsing Proposal	4.1.3	ICC Minutes 10.Dec 2015.doc File desc: Date/time: 15/01/2016 12:12:52 Size: 35 KB		
6	Signatures of ICC or HSCC or equivalent in Proposal	4.1.3	ICC Signatures.pdf File desc: Date/time: 15/01/2016 11:50:33 Size: 64 KB		
7	Minutes of last three ICC/HSCC meetings	4.1.3	ICC.rar File desc: Date/time: 15/01/2016 11:05:29 Size: 747 KB		
8	Role and functioning of the advisory group, description of plans to establish a NITAG	4.2.1	Memo on NITAG in Lesotho FINAL.docx File desc: Date/time: 15/01/2016 11:06:03 Size: 15 KB		
Planning, financing and vaccine management					
9	comprehensive Multi Year Plan - cMYP	5.1	Lesotho cMulti Year Plan 2013-2017 updated in Sept 2015 for submission.doc File desc: Date/time: 15/01/2016 11:09:31 Size: 1 MB		
10	cMYP Costing tool for financial analysis	5.1	LesothocMYP Costing data Jan 2016.xlsx File desc: Date/time: 15/01/2016 11:15:06 Size: 3 MB		

11	M&E and surveillance plan within the country's existing monitoring plan	5.1.5	NATIONAL IMMUNIZATION MONITORING TABLE LESOTHO.docx File desc: Date/time: 15/01/2016 11:15:42 Size: 16 KB
13	Introduction Plan for the introduction of RCV / JE / Men A / YF into the national programme	7.x.4	MR Introduction plan Jan 2016.doc File desc: Date/time: 15/01/2016 11:17:45 Size: 879 KB
17	Evidence of commitment to fund purchase of RCV for use in the routine system in place of the first dose of MCV	7.x.3	Government commitment to fund MR.docx File desc: Date/time: 15/01/2016 11:18:03 Size: 13 KB
18	Campaign target population documentation	7.x.1, 6.x.1	Target Population Documentation.docx File desc: Date/time: 15/01/2016 11:49:58 Size: 12 KB
19	EVM report	8.3	EVM reportKingdom of Lesotho 2014.docx File desc: Date/time: 15/01/2016 11:20:04 Size: 706 KB
20	Improvement plan based on EVM	8.3	EVMA RECOMMENDATIONS AND IMPLEMENTATION PLAN.doc File desc: Date/time: 15/01/2016 11:23:53 Size: 103 KB
21	EVM improvement plan progress report	8.3	EVM Improvement plan progress report Jan 2016.docx File desc: Date/time: 15/01/2016 11:39:33 Size: 14 KB
22	Detailed budget template for VIG / Operational Costs	6.x,7.x.2, 6.x.2	Copy of Lesotho - Detailed MR VIG Budget 2016 Final.xls File desc: Date/time: 15/01/2016 11:25:09 Size: 980 KB
27	Data quality assessment (DQA) report	5.1.5	Lesotho National Data Quality Self Assessment Report March 2012.doc File desc: Date/time: 15/01/2016 11:28:53 Size: 3 MB
29	Plan of Action for campaigns	7.1, 7.x.4	LES MSLS 2016_catch_up MR_ camp proposal final_Jan 2016.doc File desc: Date/time: 15/01/2016 11:30:32 Size: 922 KB

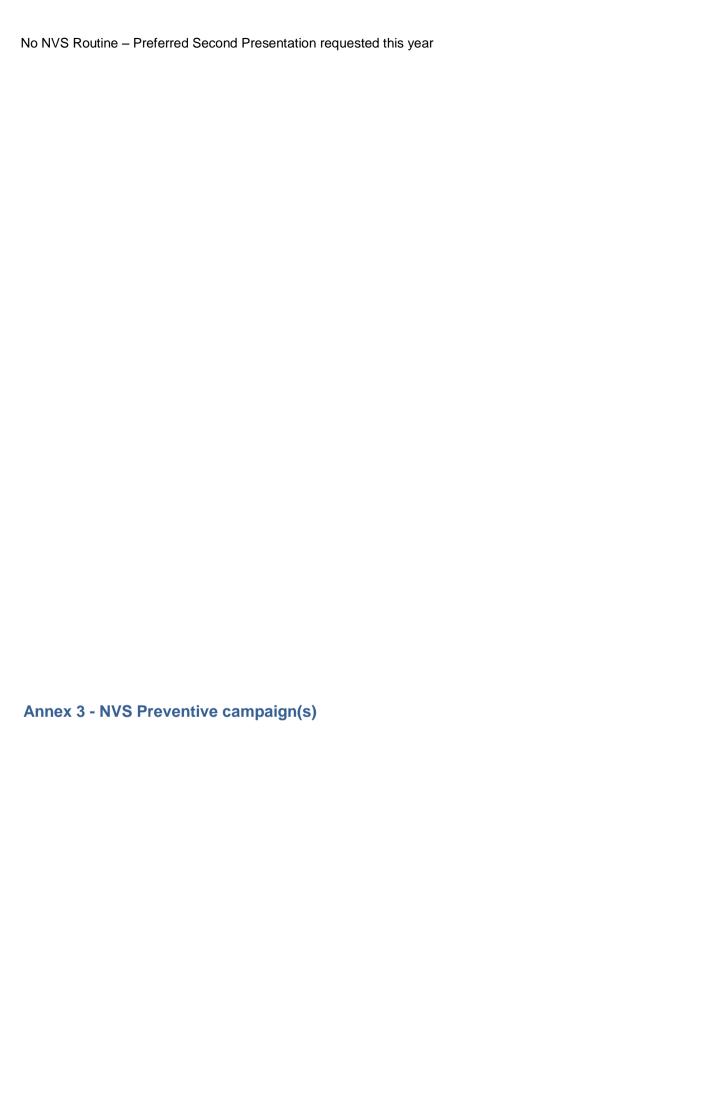
Table 2: Checklist of optional attachments

Document	Dogument	Section	File
Number	Document	Section	File

3	MoE signature (or delegated authority) of HPV Proposal	4.1.1	No file loaded
12	Vaccine introduction plan	5.1	No file loaded
15	HPV roadmap or strategy	6.1.1	No file loaded
16	HPV summary of the evaluation methodology	5.1.6	No file loaded
23	Risk assessment and consensus meeting report for MenA. If the DPT was used instead, please include this.	7.1	No file loaded
25	A description of partner participation in preparing the application	4.1.3	No file loaded
26	Minutes of NITAG meeting with specific recommendations on the NVS introduction or campaign	4.2	No file loaded
28	DQA improvement plan	5.1.5	No file loaded
30	Other		No file loaded

11. Annexes

Annex 1 - NVS Routine Support No NVS Routine Support is requested Annex 2 - NVS Routine - Preferred Second Presentation



Annex 3.1 - NVS Preventive campaign(s) (MR, 10 dose(s) per vial, LYOPHILISED) Table Annex 3.1 C: Summary table for CAMPAIGN MR, 10 dose(s) per vial, LYOPHILISED

ID		Data from		2016	2017
	Total target population	Table 5.2	#	871,822	51,664
	Number of doses per persons	Parameter	#	1	1
	Wastage Rate	Table 6.4.1	#	25	25
	Estimated vaccine wastage factor	Table 5.2	#	1.33	1.33
	Number of doses per vial	Parameter	#	10	10
	AD syringes required	Parameter	#	Yes	Yes
	Reconstitution syringes required	Parameter	#	Yes	Yes
	Safety boxes required	Parameter	#	Yes	Yes
са	AD syringe price per unit	Table Annexes 4A	\$	0.041	0.041
cr	Reconstitution syringe price per unit	Table Annexes 4A	\$	0.003	0.003
cs	Safety box price per unit	Table Annexes 4A	\$	0.005	0.005
fv	Freight cost as % of vaccines value	Table Annexes 4B	%	2.48%	2.48%
fd	Freight cost as % of devices value	Parameter	%	0	0

Table Annex 3.1 D: Estimated numbers for MR, 10 dose(s) per vial, LYOPHILISED, associated injection safety material and related co-financing budget (page 1)

		Formula	2016		
			Total	Government	Gavi
В	Total target population	Table 5.3.1	871,822	0	871,822
С	Number of doses per persons	Vaccine parameter (schedule)	1		
D	Number of doses needed	BxC	871,822	0	871,822
Ε	Estimated vaccine wastage factor	100 / (100 - Vaccine wastage rate)	1.33		
F	Number of doses needed including wastage	DxE	1,159,524	0	1,159,524
G	Vaccines buffer stock	0	0	0	0
ı	Total vaccine doses needed	Round up((F + G) / Vaccine package size) * Vaccine package size	1,159,600	0	1,159,600
J	Number of doses per vial	Vaccine parameter	10		
K	Number of AD syringes (+ 10% wastage) needed	(D + G) x 1.11	967,723	0	967,723
L	Reconstitution syringes (+ 10% wastage) needed	(I/J) x 1.11	128,716	0	128,716
М	Total of safety boxes (+ 10% of extra need) needed	(K + L) / 100 x 1.11	12,171	0	12,171
N	Cost of vaccines needed	I x vaccine price per dose (g)	702,718	0	702,718
0	Cost of AD syringes needed	K x AD syringe price per unit (ca)	39,437	0	39,437
Р	Cost of reconstitution syringes needed	L x reconstitution price per unit (cr)	395	0	395
Q	Cost of safety boxes needed	M x safety box price per unit (cs)	62	0	62
R	Freight cost for vaccines needed	N x freight cost as of % of vaccines value (fv)	17,395	0	17,395
s	Freight cost for devices needed	(O+P+Q) x freight cost as % of devices value (fd)	0	0	0
Т	Total fund needed	(N+O+P+Q+R+S)	760,007	0	760,007

Note: There is no co-financing for NVS preventive campaigns

Table Annex 3.1 D: Estimated numbers for MR, 10 dose(s) per vial, LYOPHILISED, associated injection safety material and related co-financing budget (page 2)

		Formula		2017	
			Total	Government	Gavi
В	Total target population	Table 5.3.1	51,664	0	51,664
С	Number of doses per persons	Vaccine parameter (schedule)	1		
D	Number of doses needed	BxC	51,664	0	51,664
Е	Estimated vaccine wastage factor	100 / (100 - Vaccine wastage rate)	1.33		
F	Number of doses needed including wastage	DxE	68,714	0	68,714
G	Vaccines buffer stock	0	0	0	0
ı	Total vaccine doses needed	Round up((F + G) / Vaccine package size) * Vaccine package size	68,800	0	68,800
J	Number of doses per vial	Vaccine parameter	10		
K	Number of AD syringes (+ 10% wastage) needed	(D + G) x 1.11	57,348	0	57,348
L	Reconstitution syringes (+ 10% wastage) needed	(I / J) x 1.11	7,637	0	7,637
М	Total of safety boxes (+ 10% of extra need) needed	(K + L) / 100 x 1.11	722	0	722
N	Cost of vaccines needed	I x vaccine price per dose (g)	41,693	0	41,693
0	Cost of AD syringes needed	K x AD syringe price per unit (ca)	2,338	0	2,338
Р	Cost of reconstitution syringes needed	L x reconstitution price per unit (cr)	24	0	24
Q	Cost of safety boxes needed	M x safety box price per unit (cs)	4	0	4
R	Freight cost for vaccines needed	N x freight cost as of % of vaccines value (fv)	1,033	0	1,033
s	Freight cost for devices needed	(O+P+Q) x freight cost as % of devices value (fd)	0	0	0
Т	Total fund needed	(N+O+P+Q+R+S)	45,092	0	45,092

Note: There is no co-financing for NVS preventive campaigns

Annex 4

Table Annex 4A: Commodities Cost

Estimated prices of supply are not disclosed

Table Annex 4B: Freight cost as percentage of value

Vaccine Antigen	Vaccine Type	2016	2017
MR, 10 dose(s) per	MR	2.48	2.48
vial, LYOPHILISED		%	%

Table Annex 4D: Wastage rates and factors

The following table shows the wastage rates for routine and campaign vaccines, set for 2016.

Vaccine	dose(s) per vial		n Vaccine je rate*	Benchmark Wastage Rate**
HPV bivalent, 2 dose(s) per vial, LIQUID	2	10 %	0 %	
HPV quadrivalent, 1 dose(s) per vial, LIQUID	1	5 %	0 %	
JE, 5 dose(s) per vial, LYOPHILISED	5	10 %	10 %	
Measles second dose, 10 dose(s) per vial, LYOPHILISED	10	40 %	0 %	
Meningococcal A, 10 dose(s) per vial, LYOPHILISED	10	10 %	0 %	
MR, 10 dose(s) per vial, LYOPHILISED	10	15 %	0 %	
Pneumococcal (PCV10), 2 dose(s) per vial, LIQUID	2	10 %	0 %	
Pneumococcal (PCV13), 1 dose(s) per vial, LIQUID	1	5 %	0 %	
Rotavirus, 2-dose schedule	1	5 %	0 %	
Rotavirus, 3-dose schedule	1	5 %	0 %	
Yellow Fever, 10 dose(s) per vial, LYOPHILISED	10	40 %	0 %	
Yellow Fever, 5 dose(s) per vial, LYOPHILISED	5	10 %	0 %	

Comments:

Note: HPV demonstration project wastage rates are the same as for the national introduction of the vaccine

Table Annex 4E: Vaccine maximum packed volumes

Kindly note that this table is for reference purposes only and includes Gavi- and non Gavi-supported vaccines.

Vaccine product	Designation	Vaccine formulation	Admin route	No. Of doses in the schedule	Presentation (doses/vial, prefilled)	Packed volume vaccine (cm3/dose)	Packed volume diluents (cm3/dose)
BCG	BCG	lyophilized	ID	1	20	1.2	0.7
Diphtheria-Tetanus	DT	liquid	IM	3	10	3	
Diphtheria-Tetanus- Pertussis	DTP	liquid	IM	3	20	2.5	
Diphtheria-Tetanus- Pertussis	DTP	liquid	IM	3	10	3	
DTP liquid + Hib freeze-dried	DTP+Hib	liquid+lyop.	IM	3	1	45	
DTP-HepB combined	DTP-HepB	liquid	IM	3	1	9.7	
DTP-HepB combined	DTP-HepB	liquid	IM	3	2	6	
DTP-HepB combined	DTP-HepB	liquid	IM	3	10	3	
DTP-HepB liquid + Hib freeze-dried	DTP-Hib	liquid	IM	3	10	2.5	
DTP-HepB liquid + Hib freeze-dried	DTP- HepB+Hib	liquid+lyop.	IM	3	1	22	

^{*} Source - WHO indicative wastage rates

^{**} Source - Country APRs and studies, approved by WHO, UNICEF, and the Gavi Secretariat

DTP-HepB-Hib liquid	DTP- HepB+Hib	liquid+lyop.	IM	3	2	11	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	10	4.4	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	2	13.1	
DTP-HepB-Hib liquid	DTP-HepB-Hib	liquid	IM	3	1	19.2	
DTP-Hib combined liquid	DTP+Hib	liquid+lyop.	IM	3	10	12	
DTP-Hib combined liquid	DTP-Hib	liquid	IM	3	1	32.3	
Hepatitis B	HepB	liquid	IM	3	1	18	
Hepatitis B	HepB	liquid	IM	3	2	13	
Hepatitis B	НерВ	liquid	IM	3	6	4.5	
Hepatitis B	НерВ	liquid	IM	3	10	4	
Hepatitis B UniJect	НерВ	liquid	IM	3	Uniject	12	
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	1	13	35
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	2	6	
Hib freeze-dried	Hib_lyo	lyophilized	IM	3	10	2.5	3
Hib liquid	Hib_liq	liquid	IM	3	1	15	
Hib liquid	Hib_liq	liquid	IM	3	10	2.5	
Human Papilomavirus vaccine	HPV	liquid	IM	3	1	15	
Human Papilomavirus vaccine	HPV	liquid	IM	3	2	5.7	
Japanese Encephalitis	JE_lyo	lyophilized	sc	1	5	2.5	2.9
Measles	Measles	lyophilized	SC	1	1	26.1	20
Measles	Measles	lyophilized	SC	1	2	13.1	13.1
Measles	Measles	lyophilized	SC	1	5	5.2	7
Measles	Measles	lyophilized	SC	1	10	3.5	4
Measles-Mumps- Rubella freeze dried	MMR	lyophilized	SC	1	1	26.1	26.1
Measles-Mumps- Rubella freeze dried	MMR	lyophilized	sc	1	2	13.1	13.1
Measles-Mumps- Rubella freeze dried	MMR	lyophilized	sc	1	5	5.2	7
Measles-Mumps- Rubella freeze dried	MMR	lyophilized	sc	1	10	3	4
Measles-Rubella freeze dried	MR	lyophilized	SC	1	1	26.1	26.1
Measles-Rubella freeze dried	MR	lyophilized	sc	1	2	13.1	13.1
Measles-Rubella freeze dried	MR	lyophilized	sc	1	5	5.2	7
Measles-Rubella freeze dried	MR	lyophilized	sc	1	10	2.5	4
Meningitis A conjugate	Men_A	lyophilized	IM	1	10	2.6	4
Meningitis A/C	MV_A/C	lyophilized	SC	1	10	2.5	4
Meningitis A/C	MV_A/C	lyophilized	SC	1	50	1.5	3
Meningitis W135	MV_W135	lyophilized	SC	1	10	2.5	4
Meningococcal A/C/W/	MV_A/C/W	lyophilized	sc	1	50	1.5	3

Meningococcal A/C/W/Y	MV_A/C/W/Y	lyophilized	SC	1	10	2.5	4
Monovalent OPV-1	mOPV1	liquid	Oral		20	1.5	
Monovalent OPV-3	mOPV3	liquid	Oral		20	1.5	
Pneumo. conjugate vaccine 10-valent	PCV-10	liquid	IM	3	1	11.5	
Pneumo. conjugate vaccine 10-valent	PCV-10	liquid	IM	3	2	4.8	
Pneumo. conjugate vaccine 13-valent	PCV-13	liquid	IM	3	1	12	
Polio	OPV	liquid	Oral	4	10	2	
Polio	OPV	liquid	Oral	4	20	1	
Polio inactivated	IPV	liquid	IM	3	PFS	107.4	
Polio inactivated	IPV	liquid	IM	3	10	2.5	
Polio inactivated	IPV	liquid	IM	3	1	15.7	
Rota vaccine	Rota_liq	liquid	Oral	2	1	17.1	
Rota vaccine	Rota_liq	liquid	Oral	3	1	45.9	
Tetanus Toxoid	TT	liquid	IM	2	10	3	
Tetanus Toxoid	TT	liquid	IM	2	20	2.5	
Tetanus Toxoid UniJect	тт	liquid	IM	2	Uniject	12	
Tetanus-Diphtheria	Td	liquid	IM	2	10	3	
Yellow fever	YF	lyophilized	SC	1	5	6.5	7
Yellow fever	YF	lyophilized	SC	1	10	2.5	3
Yellow fever	YF	lyophilized	SC	1	20	1.5	2
Yellow fever	YF	lyophilized	SC	1	50	0.7	1

12. Banking Form

		nancial support made by the G a electronic bank transfer as de	Government of Lesotho hereby elow:
Name of Institution (Account Holder)			
Address:			
City Country:			
Telephone no.:		Fax no.:	
	Curre	ency of the bank account:	
For credit to:			
Bank account's t	itle:		
Bank account no	.:		
Bank's name:			
Is the bank accour	nt exclusively to be	used by this program?	
By who is the acco	ount audited?		
Signature of Gove	rnment's authorizir	ng official	
			Seal
	Name:		
	Title:		
	Signature:		
	Date:		
	FINANCIAL IN	NSTITITION	CORRESPONDENT BANK
	INANOIAL	tomonon	(In the United States)
Bank Name:			,
Branch Name:			
Address:			
City Country:			
Swift Code:			
Sort Code:			
ABA No.:			
Telephone No.:			
FAX No.:			

I certify that the account No is held by at this banking institution

The accou	nt is to be signed joint	tly by at least (number of signatories) of the following authorized signatories:
1	Name:	
	Title:	
2	Name:	
	Title:	
3	Name:	
	Title:	
	•	<u>.</u>
Name of ba	ank's authorizing offici	
Signature:		
Date:		
Seal:		