Proposal Form for Gavi NVS support for India – Rotavirus vaccine

Submitted by

The Government of

India

Date of submission:

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

Start Year	2013	End Year	2017

Form revised in 2016

(To be used with Proposal and Review Process for India of March 2016)

Please submit the Proposal to: proposals@gavi.org**, with copy to the relevant Senior Country Manager at the Gavi Secretariat.**

Enquiries to: proposals@gavi.org or relevant Senior Country Manager at the Gavi Secretariat. Unless otherwise specified, the documents can be shared with Gavi partners, collaborators and the general public. The Proposal and attachments must be submitted in English.

Gavi is unable to return submitted documents and attachments to countries.

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. Proposal preparation

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
Dr Ambujam Nair Kapoor	**Senior Advisor (ITSU)**	**+919945395366**	**ambujam.kapoor@phfi.org**
Dr Pradeep Haldar	**Deputy Commissioner (Immunization), Ministry of Health & Family Welfare, Govt of India**	**+918800495771**	**pradeephaldar@yahoo.co.in**

2. Type of Support requested

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

Type of Support	Preferred first presentation[1]	Start Year	End Year	Preferred second presentation[1]
Routine New Vaccines Support	Rotavirus 10 dose vial	2017	2020	Rotavirus 5 dose vial

[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.

* Note Rotavirus vaccine presentation options:

- Rotavirus 2-dose schedule, one dose vial, LIQUID
- Rotavirus 3-dose schedule, one dose vial, LIQUID
- Rotavirus 3-dose schedule, 5-dose vial, FROZEN LIQUID
- Rotavirus 3-dose schedule, 10-dose vial, FROZEN LIQUID
- Rotavirus 3-dose schedule, 2-dose vial, LYOPHILISED

When is the country planning to introduce rotavirus vaccine (month/year)? 3rd Quarter of 2017 (Phase 3, with Gavi support)

India has already introduced Rotavirus vaccine with domestic funding in the first quarter of 2016 in four states. In Q1 2017, Government of India is planning to scale up the vaccine in five more states.

Subsequently, India is seeking Gavi support as commodity assistance to scale up the vaccine in the third phase in the state of Uttar Pradesh in Q3 2017 to cover another approximately 20% of the target population each year for three years, with supplies to be delivered to consignee points and not to port of entry. Operational cost will be borne by the Government of India. The Govt. of India will continue Rotavirus immunization in these states once Gavi support is over, as has been done in the past with pentavalent and hepatitis B vaccines. The Government of India will provide funds for scaling up the vaccine introduction in the rest of the country in a phased manner. The specific states and the timing of scale up will be decided as per availability of vaccines and funds.

3. Overview of State-wise vaccine introduction

Please provide an overview of the planned state-wise introduction of rotavirus vaccine (for Gavi-supported phases and domestically supported phases where known). Timings of introduction of other vaccines are included for reference. Information can be provided in a different format as a separate attachment.

	IPV	Rotavirus	Pneumococcal	MR campaign*
A&N ISLANDS	2016			Phase 2
ANDHRA PRADESH	2016	Phase 1 (Q1 2016)		Phase 2
ARUNACHAL PR.	2016			Phase 2
ASSAM	Q4 2015	Phase 2 (Q1 2017)		Phase 2
BIHAR	Q4 2015		2017	Phase 3
CHANDIGARH	2016			Phase 1
CHHATTISGARH	2016			Phase 3
D&N HAVELI	2016			Phase 2
DAMAN & DIU	2016			Phase 2
DELHI	2016			Phase 1
GOA	2016			Phase 2
GUJARAT	Q4 2015			Phase 3
HARYANA	2016	Phase 1 (Q1 2016)		Phase 3
HIMACHAL PRADESH	2016	Phase 1 (Q1 2016)	2017	Phase 1
JAMMU & KASHMIR	2016			Phase 1
JHARKHAND	2016			Phase 3
KARNATAKA	2016			Phase 1
KERALA	2016			Phase 1
LAKSHADWEEP	2016			Phase 2
MADHYA PRADESH	Q4 2015	Phase 2 (Q1 2017)	2018	Phase 3
MAHARASHTRA	2016			Phase 2
MANIPUR	2016			Phase 2
MEGHALAYA	2016			Phase 2
MIZORAM	2016			Phase 2
NAGALAND	2016			Phase 2
ODISHA	2016	Phase 1 (Q1 2016)		Phase 2
PONDICHERRY	2016			Phase 1
PUNJAB	Q4 2015			Phase 1
RAJASTHAN	2016	Phase 2 (Q1 2017)	2018	Phase 4
SIKKIM	2016			Phase 2
TAMIL NADU	2016	Phase 2 (Q1 2017)		Phase 1
TELANGANA	2016			Phase 2
TRIPURA	2016	Phase 2 (Q1 2017)		Phase 2
UTTAR PRADESH	Q4 2015	Phase 3 (Q3 2017)	2017	Phase 4
UTTARAKHAND	2016			Phase 1
WEST BENGAL	2016			Phase 2

* MR campaign phases 1 and 2 in 2017, and phases 3 and 4 in 2018

4. Rotavirus vaccine support

4.1. Baseline and Annual Targets (NVS Routine Support)

Please refer to cMYP pages to assist in filling-in this section.

Number	Base Year	Baseline and Targets				
	2015	2016	2017	2018	2019	2020
Total births [A]	28,338,000	26,342,000	26,246,000	26,130,000	25,996,000	25,850,000
Total infants' deaths [B]	1,340,000	1,061,000	1,057,000	1,053,000	1,049,000	1,041,000
Total surviving infants	26,998,000	25,281,000	25,189,000	25,077,000	24,947,000	24,809,000
Target population vaccinated with DTP1/Penta1*[1]*	26,921,100	25,024,900	24,933,700	24,823,500	24,696,200	24,557,500
Target population vaccinated with DTP3/Penta3*[1]*	25,504,200	23,707,800	23,621,400	23,517,000	23,396,400	23,265,000
DTP/Penta3 coverage*[2]*	90%	90%	90%	90%	90%	90%
Target population for the 1st dose of rotavirus vaccine by State (for Gavi-supported phase of introduction)						
State: Uttar Pradesh			1,411,000	5,634,000	5,620,000	4,201,500
Target population for the last dose of rotavirus vaccine by State (for Gavi-supported phase of introduction)						
State: Uttar Pradesh			1,411,000	5,634,000	5,620,000	4,201,500
Target Rotavirus Vaccine last dose coverage *[2]*	%	%	100%	100%	100%	100%
First Preferred Presentation: Rotavirus 10 dose vial						
Wastage*[3]* rate in base-year and planned thereafter (%)	%	%	25%	25%	25%	25%
Second Preferred Presentation: Rotavirus 5 dose vial						
Wastage*[3]* rate in base-year and planned thereafter (%)	%	%	25%	25%	25%	25%

Source: A and B : MoHFW

NOTES AND COMMENTS:

1. **Coverage projected to be 95% for DPT1 and Penta1 based on GoIs goals of more than 90% coverage for full immunization and 2015 WUENIC estimate of 90%.**
2. **Coverage projected to be 90% for both DPT3/Penta3 based on GoI goals and 2015 WUENIC estimates of 87%.**
3. **RVV doses have been calculated on the basis of 100% coverage in the first year of introduction with 25% buffer and 25% wastage. For subsequent years, it will be based on replacement of consumption of vaccine, assuming that the coverage is 90% and wastage is 25%. On the basis of this, the total dose of RVV vaccine required with Gavi is ~65 million doses covering on an average nearly 21% of target population each year for a period of three years. All calculations have been done using no. of births, as 1st dose of RVV is given at 6 weeks. Same principles had governed proposals submitted previously to Gavi for new vaccine introductions.**
4. **For smooth vaccine supply, any changes in price of vaccine or freight costs must be factored in by Gavi only in the last tranche of RVV supply and not in the initial stages.**
5. **All supplies are to be delivered to consignee points.**

4.2 Cold chain capacity

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. The Independent Review Committee requires assurance that the cold chain is ready or will be ready for the routine introduction of the new vaccine, and evidence/plans need to be provided. 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.

The above information can be provided as separate document(s) to describe any relevant capacity assessments and plans.

There are approximately 27,000 cold chain points in India. Introduction of Pentavalent vaccine across the country has further freed cold chain space within the existing equipment. Additionally, there is an ongoing procurement which will substantially extend the cold chain space availability sufficiently to accommodate all new vaccine introductions. With these procurements, soon the cold chain space in terms of number of ILRs and Deep Freezers is expected to increase by over 30%; walk-in coolers and walk-in freezers would increase by 8% and 26% respectively.
Training of cold chain handlers, technicians will be carried out prior to RVV introduction while ensuring there is synergy between these introductions and also with routine RI trainings.
The Government of India is implementing an alternate vaccine delivery (AVD) system, to ensure that the immunization session starts on time, vaccines are collected on the same day and unused/opened vials and immunization waste are brought to PHC on the same days. There are various ways of implementation of AVD system such as hiring of vehicle/auto-rickshaw, motor cycle/bicycle, potter, boats etc. Under the National Health Mission, flexible funds are available for the AVD system, which can be utilized based on the local conditions.
There is sufficient availability of power supply as the majority of cold chain equipment require only up to 8 hours of electricity per day. In selected areas, where power supply may be limited, solar cold chain equipment are being installed.

4.3 Integrated disease control

Gavi considers the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) an important initiative. For Gavi to develop an understanding of any existing interventions and any barriers to integration activities:

Please describe any existing interventions for the prevention and treatment of pneumonia and diarrhoea and the status of implementation.

Under the umbrella of National Health Mission (NHM), the interventions under the maternal health, child health and immunization focus on early initiation of and exclusive breast feeding, use of oral rehydration salt (ORS) and Zinc tablets in children with diarrhea, provision of Vitamin A, vaccination as per the national immunization schedule, increasing the access to health care. ORS and Zn are provided under the National Health Mission (NHM) to all cases of diarrhea seeking care at District hospitals/CHC/PHC/Additional PHC/SC. For children with non-severe pneumonia, co-trimoxazole is provided at SCs for community based management of pneumonia by front line workers. At the facility level, amoxicillin is given by the physician for non-severe pneumonia. A detailed ARI treatment guideline is being developed to assist states with standard treatment protocols and operational strategies to improve preventive and treatment services. An integrated diarrhoea and pneumonia prevention control is being implemented in Bihar, UP, Madhya Pradesh and Rajasthan with support of UNICEF & WHO. It aims to reduce mortality from pneumonia to < 3 per 1000 live births and from diarrhoea to < 1 per 1000 live births. It works on principle of PROTECT (by promoting breastfeeding and adequate complimentary feeding), PREVENT (ensuring measles vaccination, promoting hand wash with soap) and TREAT (improving care seeking behaviour and referral and ensuring improved

case management at community and health facility level). A National Consultation was held in October 2014 to take forward WHO Global Action Plan for Pneumonia and Diarrhoea (GAPPD) and develop an Integrated Action Plan for Pneumonia and Diarrhoea (IAPPD). The plan is currently being scaled up in the 62 High Priority Districts (HPDs) in four states (UP, Bihar, Rajasthan and Madhya Pradesh). Strategic planning workshops were conducted in all four of the high-priority states to review the barriers in implementation and identify optimal solutions in 2014-15. State/district level committees are being established in the four priority states and the HPDs. Planning and budgeting for roll-out of IAPPD in these states are being included in the State NHM Project Implementation Plans (PIPs).

Himachal Pradesh (HP) has been selected for PCV introduction for demonstration of combined impact of PCV and RVV vaccines (already introduced in HP in phase 1).

Ongoing support is being provided by WHO UNICEF during the operational planning for PIPs in other select states (Manipur, Haryana and Tripura) that have requested for assistance.

b) Please provide any considerations for how vaccination could strengthen delivery and communication of additional health interventions. Please highlight any barriers that you may foresee with integrating vaccination with other health interventions.

All the activities to introduce new vaccines will help enhance routine immunization programme system strengthening, especially in the areas of micro planning including high risk areas, health workers training (both of vaccinators and link workers), cold chain strengthening, improving AEFI surveillance & management using AEFI management kits, injection safety, social mobilization and immunization waste management. Recent example of Mission Indradhanush has demonstrated the same where, besides vaccination under Universal Immunization Programme (UIP), Vitamin A, ORS and Zinc were also provided.

4.4. Portion of supply to be procured by Gavi

a) Please indicate the vaccine requirement for the Gavi-supported phase of rotavirus vaccine introduction, based on the target population information provided in Table 4.1.

	2017	2018	2019	2020
No of states/union territories	1	1	1	1
Total estimated target infant population	1,411,000	5,634,000	5,620,000	4,201,500
% of total infant population	5%	22%	22%	16%
Rotavirus doses required	7,037,363	26,132,605	20,181,420	11,315,690

b) Please include any specific assumptions in calculating the vaccine requirement.

RVV doses have been calculated on the basis of 100% coverage in the first year of introduction with 25% buffer and 25% wastage. For subsequent years, it will be based on replacement of consumption of vaccine, assuming that the coverage is 90% and wastage is 25%. On the basis of this, the total dose of RVV vaccine required is ~65 million doses covering on an average nearly 21% of target population each year for a period of three years. All calculations have been done using no. of births, as 1st dose of RVV is given at 6 weeks. Same principles had governed proposals submitted previously to Gavi for new vaccine introductions. In addition, for smooth vaccine supply, any changes in price of vaccine or freight costs must be factored in by Gavi only in the last tranche of RVV supply and not in the initial stages. All supplies are to be delivered to consignee points.

4.5 Procurement for Rotavirus Vaccine (Routine)

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

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

India is seeking Gavi support for Rotavirus vaccine as commodity assistance only (through UNICEF). The syringes will be procured through Government of India' procurement procedures using its own funds. All supplies are to be delivered to consignee points.

b) If an alternative mechanism for procurement and delivery of vaccine supply (financed by the country or the Gavi) is requested, please document

- A description of the mechanism and the vaccines or commodities to be procured by the country
- Assurance that vaccines will be procured from the WHO list of pre-qualified vaccines, indicating the specific vaccine from the list of pre-qualification. For the procurement of locally-produced vaccines directly from a manufacturer which may not have been prequalified by WHO, assurance should also be provided that the vaccines purchased comply with WHO's definition of quality vaccines, for which there are no unresolved quality problems reported to WHO, and for which compliance is assured by a fully functional National Regulatory Authority (NRA), as assessed by WHO in the countries where they are manufactured and where they are purchased.

Not Applicable

4.5.2 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, and if the country would issue waivers for an importation license for a period of

time where necessary.

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

For a new vaccine introduction, it is necessary and sufficient to obtain manufacturer's registration and licensure from the Central Drugs and Standards Organization (CDSCO). The manufacturer has to submit an application in the prescribed CDSCO format for import /manufacture and marketing approval of new drugs for human use. The time taken for approval will be based on the processing time and requirements for approval process of the CDSCO.

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

Government of India prefers 10-dose vials. The preference is for the lowest cost Rotavirus vaccine which would enable us to cover the largest possible birth cohort of Rotavirus vaccine or other new vaccines supported by Gavi.

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.

The manufacturer has to submit an application for import of vaccine (as applicable) and once that is obtained, samples of the vaccine have to be sent to CDL, Kasauli for quality testing, one month prior to shipment of batches of vaccine.

Please provide information on NRA in the country, including 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.

The National Regulatory Authority of the Central Drugs and Standards Organization (CDSCO) Central Drugs and Standards Organization (CDSCO), which is headed by the Drug Controller General of India, Dr. G.N. Singh, Address: FDA Bhawan, Kotla Marg, New Delhi – 110002. Phone no: +91-1123236965, +91-1123236367. Email: dci@nic.in

5. Mandatory documents

Noting that Rotavirus vaccine has been introduced in country and that Gavi support is requested for continued expansion, please provide:

- Available administrative data on rotavirus vaccine coverage in Phase 1 states
- Relevant introduction plans or implementation review reports, to provide information on lessons learned from the initial phases of Rotavirus vaccine introduction in country.

Additional supporting documents can include e.g. AEFI/intussusception surveillance, Rotavirus expert group meeting minutes on considerations for states selection, etc. to provide information on introduction readiness.