

## **Gavi Middle Income Countries (MICs) Approach**

Support Request Guidelines & Instructions for New Vaccine Introductions: Technical Assistance support, One-Off support for vaccine introduction costs, and Vaccine Catalytic Financing

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## About this document

There are different types of support available under the Gavi Middle Income Countries (MICs) Approach. This document is designed to help countries to request support for New Vaccine Introductions of PCV, Rotavirus and HPV under the Gavi MICs Approach. Three types of support are available:

- Technical Assistance from in-country partners
- One-off support for vaccine introduction costs
- Vaccine catalytic financing

This funding is currently only available under the Gavi MICs Approach until the end of December 2025.

This document specifically provides guidance to middle-income countries and stakeholders on how to request support for these three types of support towards the **successful and equitable introduction of key missing vaccines into the country national immunisation programme**.

The guidelines are structured in the following way:

- **[Section 1: Introduction to the Gavi MICs Approach](#)**: This section provides background information about the Gavi MICs Approach, including what outcomes it seeks to achieve at a global level.
- **[Section 2: About New Vaccine Introduction support](#)**: This section describes the eligibility for support, the three different types of support available, and other considerations. Not all types of support will be relevant to all countries.
- **[Section 3: Developing the Support Request](#)**: This section provides step-by-step guidance on how to develop the different elements of the request for support to be submitted for review.

## Section 1: Introduction to the Gavi MICs Approach

The Gavi [Middle Income Countries \(MICs\) Approach](#) was approved by the Gavi Board in December 2020 and June 2022 as a key tool to address inter- and intra- country inequities in immunisation and provides the framework for Gavi's engagement in former and select never-Gavi eligible countries<sup>1</sup>. The Gavi MICs Approach contributes to Gavi's overall intended impact of leaving no one behind with immunisation. Specifically, it is expected to contribute substantively to Gavi 5.0's Strategic Goal 3: Improve sustainability of country immunisation programmes<sup>2</sup>.

The MICs Approach has two key objectives: Firstly, **to prevent and mitigate backsliding in vaccine coverage in former-Gavi eligible countries**, and secondly, to **drive the sustainable introduction of key missing vaccines (PCV, rotavirus and HPV vaccines) in both former and select never Gavi-eligible countries**. Under these objectives, the MICs Approach has three long-term outcomes, and seven intermediate outcomes.

<b>Objective 1</b>	Support sustainable introduction of key missing vaccines in former and never Gavi countries
<b>Long term outcome</b>	PCV, rotavirus and HPV vaccines sustainably introduced in national immunisation programmes
<b>Objective 2</b>	Prevent and mitigate backsliding in vaccine coverage in former-Gavi countries
<b>Long term outcome</b>	Immunisation system performance is maintained, sustainable, and resilient to shocks and stresses
<b>Long term outcome</b>	Coverage rates restored, including by reaching zero-dose children
<b>Intermediate outcome 1</b>	Sustainable access to PCV, rotavirus and HPV vaccines
<b>Intermediate outcome 2</b>	Routine immunisation services restored and reinforced to catch up missed children
<b>Intermediate outcome 3</b>	Zero-dose children identified and targeted in reinforcement of routine immunisation services
<b>Intermediate outcome 4</b>	Community demand for & confidence in vaccines and immunisation services, including among missed communities
<b>Intermediate outcome 5</b>	Institutional capacities to plan and deliver sustained, equitable immunisation programmes, as a platform for broader PHC delivery
<b>Intermediate outcome 6</b>	Sufficient, sustained, and reliable domestic resources for immunisation programmes
<b>Intermediate outcome 7</b>	Political commitment to & accountability for equitable immunisation (including zero-dose agenda) at national & subnational levels

<sup>1</sup> Former Gavi-eligible countries are countries that have previously been Gavi-eligible and have transitioned from that support. These countries are referred to in this document as 'former-Gavi'. Never Gavi-eligible countries are those that have never been Gavi-eligible. These countries are referred to in this document as 'never-Gavi'. The list of former- and never- Gavi eligible countries that are eligible for support under the MICs Approach can be found [here](#).

<sup>2</sup> For more information on Gavi's 5.0 strategy see [here](#).

The long-term and intermediate outcomes are used to decide upon, and measure, the support provided through the Gavi MICs Approach<sup>3</sup>. To achieve these outcomes, there are **several types of support** available to countries and partners:

**Table 1: Types of support available**

Objective	Type of support available	Brief description of support type (Please refer to the support guidelines for more detailed information)
<b>Support the sustainable introduction of key missing vaccines in former and select never Gavi countries</b>	<b>In-country technical assistance</b>	Support via relevant in-country and national partners, including CSOs, academic institutions and others as appropriate, to drive forward sustainable and equitable new vaccine introductions
	<b>One-off support for vaccine introduction costs</b>	Funding to help cover specific one-off costs directly related to ensuring the success of a new vaccine introduction
	<b>Vaccine catalytic financing</b>	One-off vaccine financing for doses to cover half of the first single-age target cohort for a new vaccine introduction
	<b>Pooled procurement mechanisms</b>	Assistance accessing pooled procurement mechanisms in collaboration with UNICEF Supply Division towards the achievement of more sustainable vaccine prices
<b>Prevent and mitigate backsliding in vaccine coverage in former Gavi countries</b>	<b>Targeted Interventions</b>	Catalytic support to help former-Gavi countries make sustainable and equitable improvements to coverage rates by addressing key drivers of backsliding and by reaching zero-dose children. Countries can also request funding for technical assistance through local partners, including CSOs, to support them in their efforts to reach zero-dose children and restore coverage.
<b>Towards both objectives</b>	<b>Regional and multi-country Technical Assistance</b>	Regional and multi-country technical assistance via core and expanded partners to support the sustainability of routine immunisation programmes. Activities are designed to address common challenges to prevent backsliding and/or support new vaccine introductions by recognising country needs. Activities are to be provided by those partners demonstrably best placed to do so.
	<b>Supporting peer-to-peer learning among middle-income countries</b>	<p>The Linked Immunisation Action Network, funded under the MICs Approach, is a Gavi-supported peer-to-peer learning network dedicated to supporting middle-income countries. Countries are provided with opportunities to connect and learn from one another's experiences: <a href="http://www.linkedimmunisation.org/">www.linkedimmunisation.org/</a></p> <p>Gavi also supports other peer-to-peer learning networks and communities of practice which offer support to countries on critical issues, such as the <a href="#">Vaccine Procurement Practitioners Network</a> and the <a href="#">Zero-Dose Community of Practice</a>.</p>

Support types covered in these guidelines

<sup>3</sup> The Gavi MICs Approach objectives, long-term and intermediate outcomes are presented in a global-level Theory of Change for the MICs Approach and its accompanying narrative. These can be found [here](#).

The MICs Approach is accompanied by a Learning Agenda which seeks to understand what works best in supporting countries and why, in line with the MICs Approach [Theory of Change](#).

## Getting started

Countries should start by first establishing (or reviewing) their own in-country strategy and plans for introducing new vaccines including, once available, a new vaccine introduction plan. **The common ground between what the country seeks to achieve, and what the Gavi MICs Approach seeks to achieve, is where the opportunity lies for the country and Gavi to work together.**



## Existing Gavi guidance

Gavi has developed [guidance for Gavi-eligible countries](#) to support with the development of Gavi support requests. Some of this material may also be instructive for MICs-eligible countries when developing their support requests for New Vaccine Introduction Technical Assistance support and One-off costs. In particular, countries may be interested to review the following resources, **noting that the target audience for these materials are Gavi-eligible countries, and therefore not all aspects are relevant:**

- [Detailed Product Profiles](#): Aims to provide countries with easy access to up-to-date and comprehensive information on Gavi-supported vaccines.
- [Gavi vaccine funding guidelines](#): Provides information on how Gavi supports Gavi-eligible countries with the introduction of vaccines, including links to external resources on HPV, PCV and Rota such as WHO guidelines and recommendations
- [Gavi Programme Funding Guidelines](#): Provides guidance on support for Gavi-eligible countries, as well as other helpful guidance on areas to consider and how to, e.g. ensure a gender focus. Includes reference to useful technical documents from WHO, UNICEF and other partners
- [Zero-dose analysis card](#): Assists with and/or consolidate analyses to help countries identify and design service delivery approaches to sustainably reach zero dose children and missed communities.
- [Immunisation Financing – considerations for country dialogue](#): Examines issues to consider with respect to (i) planning and budgeting, (ii) securing funding for immunisation, (iii) disbursing and executing available resources, and (iv) accounting for and reporting on domestic expenditures

- [Gavi Guidelines on National Coordination Forums](#): Recognising the critical role of Coordination Forums (ICC/HSCC or equivalent), Gavi has developed guidance to help countries strengthen Coordination Forums functioning to better support national immunisation and health sector goals

Countries may also be interested to review the Alliance compendium of [Technical Resources for Improving Immunisation Coverage and Equity](#), hosted by Technet21. This database compiles technical resources (tools, technical guidance, information documents and databases) for improving coverage and equity of immunization services. Intended users of the database include managers of national immunization programs and EPI & PHC technical advisers and partners.

## Section 2: About New Vaccine Introduction Support

### *i. Scope of Support*

The Gavi MICs Approach offers a suite of support to help countries drive new vaccine introductions of **PCV**, **rotavirus** and **HPV** vaccines into national immunisation programmes. Support is not available for the introduction of other vaccines nor is it available to support switching to different products or presentations of already-introduced vaccines.

This suite of support comprises three parts:

1. **Technical Assistance from in-country partners:** Support via relevant in-country and national partners, including CSOs, academic institutions and others as appropriate, to drive forward sustainable and equitable new vaccine introductions
2. **One-off support for vaccine introduction costs:** Funding to help cover specific one-off costs directly related to ensuring the success and equity of a new vaccine introduction
3. **Vaccine Catalytic Financing:** One-off vaccine financing for doses to cover half of the first single-age target cohort for a new vaccine introduction where this has a meaningful and positive impact on a new vaccine introduction.

Further details about the scope of each of these three types of support is provided below.

In general, countries should take the following elements into consideration when developing their requests for support:

- Proposed activities for technical assistance and one-off costs should be evidence-based and plans must demonstrate that there is a genuine opportunity for Gavi's investment to have a meaningful impact on driving sustainable and equitable new vaccine introductions.
- Countries are also encouraged to innovate, e.g., to scale up new approaches, services, and technologies and to develop new partnerships with a broad range of stakeholders.
- Countries should consider how they will systematically monitor and learn over the course of implementation, and how these learnings will be used to iterate and course-correct during the period of support and beyond.
- Countries receiving support from Gavi for a new vaccine introduction under the MICs approach are required to conduct a post-introduction evaluation. The evaluation report must be shared with Gavi within one year of the new vaccine introduction. Note that Technical Assistance support can be requested to support with this.
- In the case of HPV, support is only available for introductions for a single-age cohort of girls between the ages of 9 to 14 years.

Finally, countries are requested to consider how they can share their experiences with other MICs-eligible countries via the Linked Immunisation Action Learning Network: <https://www.linkedimmunisation.org/>

### *ii. Eligibility and entitlements*

All former Gavi-eligible countries, never Gavi-eligible lower middle-income countries, and IDA-eligible economies that have not yet introduced PCV, rotavirus and/or HPV vaccines into their national<sup>4</sup> routine immunisation programme are eligible for support towards the introduction of these key missing vaccines. See [here](#) for the list of countries that are eligible for this support.

<sup>4</sup> Countries that have only introduced these vaccines sub-nationally (i.e. into select regions or districts) are also eligible for support to take the introduction nationwide.



It is important to note that whilst these countries are eligible for support, no country or partner is 'entitled' to support nor is there a dedicated amount of funding assigned to each country. Thus countries, partners and the Secretariat will together identify how the support available under the MICs Approach can most effectively and impactfully support countries to tackle their priority needs towards sustainably and equitably introducing new vaccines. All funding awards under the MICs Approach must tangibly contribute to the objectives of the MICs Approach and align with the [Theory of Change](#). For example, vaccine catalytic financing is only appropriate in cases where it can be shown that it will have a positive impact on a new vaccine introduction. The final decision will depend on where a country is at on their new vaccine introduction journey and how support from Gavi can meaningfully contribute.

### *iii. Timing of support*

- **Technical Assistance and One-Off costs:** Support can be requested from Gavi to cover the cost of activities that take place by the 31 December 2025
- **Vaccine Catalytic Financing:** Funding for vaccine catalytic financing can be requested from Gavi to fund the costs of eligible vaccine doses as long as these vaccines have been committed on Purchase Order by one of Gavi's approved procurement partners (UNICEF SD and PAHO RF) by 31 December 2025. Note that there are several key steps that must take place in advance of this. Please contact your SCM for details.

Gavi is willing to support phased introductions, i.e., where the introduction is scaled up over a number of years, provided that there is a written government commitment to a national introduction and a clear plan in place. If the country is applying for support for a phased introduction, evidence of this commitment to a national introduction should be included as part of the request for support. In the case of a phased introduction, Vaccine Catalytic Financing may be requested to cover a full (nationwide) cohort provided that these vaccines have been committed on Purchase Order by one of Gavi's approved procurement partners (UNICEF SD and PAHO RF) by 31 December 2025<sup>5</sup>.

### *iv. Phasing of support requests*

Gavi recognises that given the nature of new vaccine introductions, not all support needs will be able to be identified upfront. Countries are encouraged to submit as comprehensive a proposal as possible (in order to reduce transaction costs) but can, should they wish, submit several iterative requests for support if there is uncertainty over future funding needs.

**Example:** Country wishes to introduce PCV vaccine in June 2024 but has not yet developed a new vaccine introduction plan. In March 2023 the country requests Gavi funding for technical assistance from an in-country partner to help develop the plan. The plan is completed in August 2023 and identifies a series of critical activities to support the new vaccine introduction. In October 2023 the country submits a further request for Gavi support, including technical assistance and one-off costs to fund some of these activities. At the same time, they submit a request for vaccine catalytic financing.

<sup>5</sup> Note that there are several key steps that must take place in advance of this. Please contact your Senior Country Manager for details.



#### *v. Technical Assistance via in-country partners*

In considering the different steps required to successfully introduce a new vaccine, a country may identify that they require technical assistance support from in-country partners. Technical Assistance support can be requested by countries both before and after a formal decision has been taken to introduce the vaccine.

Given the significant differences in country contexts between MICs, **Gavi does not articulate what kinds of technical assistance activities are in scope for this support**. This provides the space for countries to self-define and prioritise, alongside partners, which activities are most relevant in their contexts depending on where focus is most needed. **However, activities must clearly address an identified need and must also logically and meaningfully contribute to the success, sustainability and equity of new PCV, rotavirus and/or HPV vaccine introductions as per the objectives and desired outcomes of the MICs Approach.**

As a non-exclusive guide, examples of potential technical assistance could include:

- Conducting cost-effectiveness analyses
- Assessing product choice
- Developing a (costed) new vaccine introduction plan, including by conducting zero-dose and gender analysis to inform evidence-based plans that reach all children
- Forecasting national budgetary requirements for vaccines and associated supplies
- Developing a health worker training programme on new vaccine introductions
- Community engagement and communication, improving services to clients with improved health worker communication, empathy, and understanding
- Developing communication and social mobilisation plans and materials for the introduction of new vaccines and reaching zero-dose children
- Designing evidence-based, context-specific behaviour change initiatives to effectively inform communities and increase vaccine demand
- Developing routinised plans for reaching traditionally missed communities
- Integrating new vaccines into national health management information systems (HMIS)
- Generating evidence on the economic benefits of sustaining new vaccines
- Conducting post-introduction evaluations

Whenever possible, activities related to multiple new vaccine introductions should be coordinated and integrated to create synergies and cost-savings.

Whilst Gavi funding can be requested to finance the costs of expert consultants and/or time-limited staff, these costs must be linked to concrete deliverables. Gavi will not fund ongoing, recurrent, unspecified, or indeterminate human resource costs or incentives nor, under 'Technical Assistance', will Gavi fund implementation or delivery costs (these costs may be eligible under 'One Off costs', see below). Note that Technical Assistance to increase the coverage of vaccines which have already been introduced nationwide is not eligible for support<sup>6</sup>.

Countries are strongly encouraged to think broadly about which in-country partners are best placed to provide this technical assistance. Potential partners could include WHO, UNICEF,

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<sup>6</sup> Note that countries that have only introduced these vaccines sub-nationally (i.e. into select regions or districts) are eligible for support to take the introduction nationwide.

the World Bank, non-governmental organizations, civil-society organisations, academic institutions, and the private sector. Gavi is particularly keen to see a broad range of in-country partners be involved, including CSOs, academic institutions, youth and women health organisations etc.

### **Spotlight on CSOs**

Civil society participation was critical to the planning, execution, and monitoring of HPV vaccine introduction in **Bolivia**. In the city of Sucre, CSOs participated in HPV vaccine orientations and led community-based immunisation promotion. To promote equitable reach of the vaccine, CSOs also assisted healthcare personnel with identifying and targeting unvaccinated, vaccine-eligible students and unenrolled individuals who would otherwise be missed by the school-based delivery strategy.

A key objective of Technical Assistance is to build and strengthen in-country capacity. Gavi is especially interested to understand how technical assistance support will contribute to building and sustaining in-country capacity (e.g., of EPI and other relevant government institutions/departments, including at subnational level) to build the skills inside of government and better enable future new vaccine introductions. Gavi also welcomes proposals that include activities to build the capacity of in-country partners, e.g. CSOs, as a step towards building a sustainable, in-country ecosystem of support.

Gavi and partners can support countries to identify and prioritise the most relevant and impactful activities to propose for Gavi funding. Countries are strongly encouraged to work with their Gavi Senior Country Manager (SCM) on the development of the support request.

Countries should develop their proposals for an implementation period to be completed by no later than 31 December 2025.

Requests for Technical Assistance are subject to review by the Gavi CEO. Please contact your SCM for details about application deadlines.

### *vi. One-off support for vaccine introduction costs*

Gavi recognises that there are specific, time-limited and one-off activities associated with the successful introduction of a new vaccine into the national routine immunisation programme which, in some countries, can be challenging to fund from domestic or other funds. Where the inability to undertake these activities threatens the success (and equity) of a new vaccine introduction, Gavi may provide one-off support to meet the cost of these delivery and implementation activities.

This support is specifically designed to cover a share of the time-limited activities needed to sustainably and equitably introduce a new vaccine. Recurrent costs that occur year after year are not eligible for support.

Activities being requested for this kind of support must be:

- Directly related to the actual introduction of the vaccine and speak directly to activities identified within a new vaccine introduction plan
- A one-time, unique activity
- Critical for the success of a new vaccine introduction

Given the significant differences in country contexts between MICs, **Gavi does not articulate what kinds of one-off costs are in scope for this support.** This provides the space for

countries to self-define and prioritise which activities are most relevant in their contexts, depending on where focus is most needed. However, **activities for which support is requested must be included as part of the country's new vaccine introduction plan** and must clearly address an identified need and must also logically and meaningfully contribute to the success of a new PCV, rotavirus and/or HPV vaccine introduction as per the objectives and desired outcomes of the MICs Approach.

As a non-exclusive guide, examples of potential support could include:

- The cost of health worker training to support the new vaccine introduction
- The cost of producing communication materials and / or delivering a communication/sensitisation campaign to support the new vaccine introduction

Whenever possible, activities related to multiple new vaccine introductions should be coordinated and integrated to create synergies and cost-savings.

Gavi will **not** fund ongoing or recurrent costs such as vaccine delivery costs, recurrent salaries and incentives, ongoing maintenance costs for vehicles or cold-chain equipment, habitual health products and consumables, or costs that are not directly linked to the introduction of a new vaccine (e.g. costs which are associated with improving coverage of an already nationally introduced vaccine, or costs associated with strengthening wider cold chain). Gavi will also not fund non-antigen specific costs, e.g. to improve supply chain, cold chain and stock management systems (including supply chain management) for all antigens.

**Requests for One-off support are dependent on the country already having the following pieces in place.** The country will need to attach evidence of meeting these requirements as part of their request for support:

- A formal decision by the Ministry of Health to introduce the vaccine
- Any required legislative changes, or that these are in process and will be completed in the next 6 months
- If the country has a NITAG, the NITAG recommendation on the vaccine introduction
- If national registration of the vaccine is required in addition to WHO PQ, confirmation that this has been done or is in process and will be completed in the next 6 months.
- A finalised New Vaccine Introduction plan
- A multi-year procurement and financing plan to ensure the ongoing and timely supply of vaccine doses. Countries are strongly encouraged to engage with UNICEF SD or PAHO RF for this long-term procurement plan.

Countries are encouraged to leverage new vaccine introductions to strengthen vaccine delivery and increase routine immunisation coverage across antigens. In particular, introductions should be designed and costed to identify strategies to find and reach children persistently missed by the immunisation programme, ensuring they benefit from vaccines as they are at much higher risk of diseases, deaths, and medical impoverishment. However, this support is not intended for longer-term system investment.

Gavi and partners can support countries to identify and prioritise the most relevant and impactful activities. Countries are strongly encouraged to work with their Gavi Senior Country Manager (SCM) on the development of the support request.

Countries should develop their proposals for an implementation period to be completed by no later than 31 December 2025.

Requests for One-Off support are subject to review by the Gavi Independent Review Committee. Submissions to the IRC are subject to application deadlines. More information,

including the application deadlines, can be found here: <https://www.gavi.org/our-support/irc>

*vii. Vaccine Catalytic Financing*

**Note:** Countries should not prepare requests for Vaccine Catalytic Financing unless this has been agreed with Gavi in advance. Countries are strongly encouraged to work with their Gavi Senior Country Manager (SCM) to determine if Vaccine Catalytic Financing is an appropriate tool to support a successful new vaccine introduction. Please contact your Senior Country Manager for more information

Under the MICs Approach, countries are themselves responsible for financing the ongoing cost of vaccine procurement for new vaccine introductions. However, Gavi recognises that some countries can find it helpful to have some initial financial support at the outset of a new vaccine introduction to help e.g., make the move from a 'decision' to the 'introduction' itself, to accelerate the timing of the introduction, to improve the equity of an introduction, and/or to help build the financial investment case with the Ministry of Finance. Whilst there is no automatic country entitlement to this support, it is available where it is expected to have a meaningful and positive impact on a new vaccine introduction, i.e. to:

- Help secure a formal decision to introduce
- Serve as a tool in the Ministry of Health's negotiations with the Ministry of Finance
- Bring forward the date of introduction, or
- Improve the equity of the introduction.

Generally, as a country advances on the pathway to introducing a new vaccine, it becomes less likely that vaccine catalytic financing is an appropriate form of support, as there is less opportunity for it to make a difference in line with its intended spirit.

Further, this financial support is:

- Only available for a new nationwide vaccine introduction. It is not available to scale up coverage of an existing nationally-introduced vaccine<sup>7</sup>.
- Only available for PCV, Rotavirus or HPV for half of the first single age target cohort, based on the schedule of the country's preferred product<sup>8</sup>. HPV support is only available for a single age-cohort of girls between the ages of 9 to 14 years.
- Is only available for countries via one of Gavi's approved procurement partners (UNICEF SD and PAHO RF) and at a price per dose established through them.
- Only available for vaccines that have been committed on Purchase Order by one of Gavi's approved procurement partners (UNICEF SD and PAHO RF) by 31 December 2025.

**Example 1:** A country wishes to introduce HPV vaccine for girls aged 9-13 from January 2024. Gavi will finance half of the number of doses required for girls aged 9 in 2024 through one of Gavi's approved procurement partners.

**Example 2:** A country wishes to introduce PCV vaccine from January 2024. Gavi will finance half of the number of doses required for the estimated birth cohort in 2024 through one of Gavi's approved procurement partners. The country requests that the award is split over two years and so the country receives half of the award for 2024 and the other half for 2025.

<sup>7</sup> Vaccine Catalytic Financing can be requested to support a nationwide expansion of a vaccine that was previously only introduced regionally/in certain districts. In such instances only the half of the single age target cohort of the new geographies would be eligible for vaccine catalytic financing.

<sup>8</sup> Note that Gavi will support the country's preferred product, regardless of the number of doses per schedule.

In addition to the cost of vaccine doses (including allowing for wastage) to cover half of the first single age target cohort, Gavi will also cover the associated cost of consumables (syringes & safety boxes), freight and costs associated with procurement through a Gavi-approved procurement partner (e.g. the handling fee). Countries can choose to take advantage of this funding either in a single instalment or in two instalments over two years provided that the vaccines have been committed on Purchase Order by the approved procurement partner by 31 December 2025. The amount is the same, regardless of the number of instalments. Shipment planning will be done in coordination with the procurement agency (PAHO or UNICEF). Please be aware that safe injection equipment shipment requires up to 5 months lead time, and shipment schedules should be planned accordingly.

**Requests for Vaccine Catalytic Financing is dependent on the country already having the following pieces in place.** The country will need to attach evidence of meeting these requirements as part of their request for support:

- A formal decision by the Ministry of Health to introduce the vaccine
- Any required legislative changes, or that these are in process and will be completed in the next 6 months
- If the country has a NITAG, the NITAG recommendation on the vaccine introduction
- If national registration of the vaccine is required in addition to WHO PQ, confirmation that this has been done or is in process and will be completed in the next 6 months.
- A finalised New Vaccine Introduction plan
- A multi-year procurement and financing plan to ensure the ongoing and timely supply of vaccine doses. Countries are strongly encouraged to engage with UNICEF SD or PAHO RF for this long-term procurement plan.

Requests for Vaccine Catalytic Financing are subject to review by the Gavi Independent Review Committee. Submissions to the IRC are subject to application deadlines. More information, including application deadlines, can be found here: <https://www.gavi.org/our-support/irc>

### *viii. Approval and Grant arrangements*

Once a request for support is submitted and approved by Gavi, Gavi will send the Government a Decision Letter outlining the support that has been approved alongside the programme terms and conditions. The country will need to sign and return this for the support to be disbursed. Following this, the formal process of agreeing the grant arrangements will begin. More details will be provided as and when appropriate, but meanwhile, countries and partners are made aware of the following points:

- Requests for support should be submitted to Gavi by a country Government entity (e.g. Ministry of Health) regardless of which entity is implementing the activities. This is to ensure that countries retain ownership and oversight of the programme.
- Funds for Technical Assistance and Vaccine Catalytic Financing will be disbursed directly to partners as appropriate.
- Funding for one-off support costs may be disbursed to either governments or partners, noting that in some instances it may be expedient to disburse to partners for contracting purposes.
- For Technical Assistance and One-off support costs, programme management costs (also known as 'admin' or 'overhead' costs) are not expected to exceed 7-8%.



#### *ix. Gavi MICs approach, equity, and gender equality*

Equity- and gender-related barriers limit immunisation service demand, use, coverage, and impact. Common barriers that can prevent caregivers from bringing their children for immunisation include:

- The lack of decision-making power
- Inadequate time and funds to access services
- The lack of information or misinformation, and
- Poor treatment by health workers

Understanding equity- and gender-related barriers can help countries ensure that PCV, rotavirus and HPV introductions are successful by adapting strategies for maximum reach, especially when it comes to zero-dose children. Therefore, in the context of the MICs approach, Gavi support can be used to inform parents and communities of the value of PCV, rotavirus and HPV immunisation, increase trust in the safety and effectiveness of vaccines and confidence in the quality and reliability of the services, generate active demand and ownership for immunisation services and to overcome equity- and gender-related barriers to immunisation (e.g., by making it easier for mothers to bring their children for vaccination).

For more information on gender programming, please see the [UNICEF practical guide to integrating a gender lens into immunisation programmes](#), the [Little Jab Aid for Covid-19 vaccination](#)<sup>9</sup> and the [Gavi Alliance Gender Policy](#). See also a recently published [UNICEF case study](#) which provides insight on how to positively impact vaccine attitudes by applying data insights, testing and scaling online vaccine communication interventions in Indonesia. Finally, this [report from UNICEF](#) describes six case studies of where gender has been integrated into immunisation demand in Liberia, Mozambique, Pakistan, Rwanda, Sudan and Yemen.

#### **Country examples of equity and gender programming relevant for supporting a new vaccine introduction**

Many countries experienced vaccine hesitancy among their population when introducing COVID-19 vaccines. In response some countries, such as **Sudan**, used social listening to understand the underlying reasons for this hesitancy. Through social listening Sudan was able to identify specific sub-groups that were particularly hesitant as well as helping to inform gender-responsive messaging. When it comes to PCV, rotavirus, and/or HPV vaccination, for example, social listening could be utilised to provide a space for communities' concerns to be voiced and increased engagement through social media.

**Monrovia, Liberia**, is home to many zero-dose children. Children miss their basic vaccinations because clinic opening hours make it difficult for working parents to bring their child to the health facility. To increase coverage, intensive immunisation outreach sessions were implemented that included after-hours vaccination drives in marketplaces. In this context, the planning of the new vaccine introduction should leverage this adapted outreach model to maximise reach.

Additional country examples are available on [Gavi's webpage on Gender and Immunisation](#).

<sup>9</sup> While this document focuses on Covid-19 vaccination, many of the proposed strategies apply to routine immunisation.



## Section 3: Developing the Support Request

A Support Request comprises of four elements:

1. A Concept Note
2. A Costed Workplan for Technical Assistance and One-off Support
3. A 'Dose Request' for Vaccine Catalytic Financing
4. An Accountability Framework

The type(s) of support a country is applying for determines which (parts of) elements the country should complete:

**Table 1: Support Request elements required for each type of support requested**

		Support Request element			
		Concept Note	Costed Workplan	'Dose Request' for Vaccine Catalytic Financing	Accountability Framework
Type of support being requested	Technical Assistance	Required: All sections <u>except</u> 10	Required	Not required	Required: Sections 1, 2 and 3 only
	One-off support for vaccine introduction costs	Required: All sections <u>except</u> 9 or 10	Required	Not required	Required: Sections 1, 2 and 3 only
	Vaccine Catalytic Financing	Required: All sections <u>except</u> 3 and 9	Not required	Required	Not required at application stage <sup>10</sup>

Countries should work in collaboration with in-country partners and stakeholders to identify the support needs to be requested to Gavi for funding. Gavi strongly encourages countries to work with a broad range of stakeholders when developing the requests for support.

**A reminder on phasing:** Gavi recognises that given the nature of new vaccine introductions, not all support needs can be identified upfront. Countries are encouraged to submit as comprehensive a proposal as possible (to reduce transaction costs) but can, should they wish, submit several iterative requests for support if there is uncertainty over future funding needs.

**Please note that Gavi will not review Support Requests without the relevant signatures as part of the Concept Note. Gavi will also not review Support Requests for One-off support for vaccine introduction costs nor Vaccine Catalytic Financing without the country presenting the required pre-requisites listed in this guidance in section 2 above. As a reminder, these are the following items:**

- ✓ A formal decision by the Ministry of Health to introduce the vaccine

<sup>10</sup> Countries will be required to complete section 4 for reporting purposes post-introduction

- ✓ Any required legislative changes, or that these are in process and will be completed in the next 6 months
- ✓ If the country has a NITAG, the NITAG recommendation on the vaccine introduction
- ✓ If national registration of the vaccine is required in addition to WHO PQ, confirmation that this has been done or is in process and will be completed in the next 6 months.
- ✓ A finalised New Vaccine Introduction plan
- ✓ A multi-year procurement and financing plan to ensure the ongoing and timely supply of vaccine doses. Countries are strongly encouraged to engage with UNICEF SD or PAHO RF for this long-term procurement plan.

**Final country Support Requests must be formally submitted by email, by a country Government representative (e.g. from the Ministry of Health) to [proposals@gavi.org](mailto:proposals@gavi.org), copying the relevant Senior Country Manager.**

## 1. The Concept Note

**Reminder:** as per Table 1, the Concept Note should be completed as follows for the different support elements:

<b>Technical Assistance</b>	Required: All sections <u>except</u> 10
<b>One-off support for vaccine introduction costs</b>	Required: All sections <u>except</u> 9 or 10
<b>Vaccine Catalytic Financing</b>	Required: All sections <u>except</u> 3 and 9

The Concept Note should be presented using the word template provided, “MICs\_NVI Combined\_Concept note\_vF”. The Concept Note consists of 12 sections:

- 1. Basic information**, including the name of the country, the vaccine introduction(s) for which support is being requested, and the contact details for the country focal point
- 2. Background to the support request**, describing what progress (if any) the country has already made towards introducing a new vaccine.
- 3. Challenges or barriers faced, and request for Technical Assistance and/or One-off support for vaccine introduction costs**, outlining:
  - what challenges or barriers the country is currently facing to proceed with the new vaccine introduction and to ensure a successful and sustainable new vaccine introduction
  - what support is requested to help overcome these challenges or barriers
  - how the requested support will help to address these, and
  - the proposed implementing partner (e.g. MoH, UNICEF, WHO, etc) which is best placed to provide this support and why.

When completing this table please explicitly describe how the proposed activities will address the identified challenge and lead to the desired result. Note that countries are strongly encouraged to consider a broad set of partners when identifying who is best placed to support the country with the new vaccine introduction. Gavi is especially interested in supporting countries to work with new and/or expanded partners.

## **Examples of equity- and gender-related barriers and interventions**

### **Barriers:**

- In some contexts, communities, and particularly women, face limited mobility to reach health facilities often compounded by a lack of time. This can make it challenging for households to prioritise vaccination.
- In some settings, communities, including women, may feel more comfortable (or obliged) to receive medical care from individuals who belong to the same ethnic group and/or of same gender.
- Mothers may not be the ones making the choice about whether their children are vaccinated. The vaccination decision may be determined by the man of the household or an elder family member.
- Misinformation and general anxiety around side effects of the vaccine can impact uptake of the vaccine. For example, when it comes to HPV vaccination, parents may be worried about its effect on fertility.
- Some communities, by virtue of being geographically isolated, may feel that their children are at a lower risk of catching vaccine-preventable diseases, and therefore less need for the vaccine.
- Female health workers may not have a representative voice in service design and oversight
- Female adolescents may be discriminated against by healthcare workers as a result of prejudices against unwed and young mothers and therefore not receive a good service

### **Learnings from vaccine introductions to improve equity and gender programming:**

- When a new vaccine is introduced there is generally renewed interest in the immunisation programme among the population. Thus there is an opportunity to deliver broader routine immunisation improvement messages. Crafted messages need to address equity- and gender- related barriers. This point should be emphasised with health staff and mobilisers prior to and during the vaccine introduction.
- Use the training on new vaccines as an opportunity to refresh knowledge and skills on disease-specific prevention and control of all other diseases preventable by routine vaccines. Positive user experience is incredibly important in building trust in targeted communities, including those who are marginalised.

- 4. Complementary activities and support**, describing other efforts underway in country, and complementary funding streams, to support the new vaccine introduction, including any previous Gavi support.
- 5. Opportunities to leverage new vaccine introductions to strengthen the immunisation programme**, describing how the country, through this/these new vaccine introductions, sees and plans to realise the potential to strengthen routine immunisation programmes, and possibly even wider primary health care systems, through this/these new vaccine introductions.
- 6. Looking ahead**, outlining what the next steps in the process are towards introducing this/these new vaccine(s) and anticipated timelines.
- 7. Risks and mitigation**, describing any risks foreseen in the implementation of the requested support and mitigations planned.
- 8. Monitoring, reporting, and learning**, outlining how the implementation of the requested support will be monitored by all partners involved, and how any needed course-corrections will be decided and actioned. In addition, if relevant please also describe how the proposed activities build on any previous similar activities and learnings from that experience

**Applying an equity and gender lens to monitoring and learning:** multiple tools were developed and/or adapted to support countries' monitoring efforts towards the reduction of zero-dose children. Countries are encouraged to use these resources in the development of their proposal:

- The [UNICEF Immunisation, Gender and Equity tool](#) maps both strategies used by countries to promote equitable access to immunisation and learning activities to be implemented for monitoring purposes
- UNICEF has identified 17 metrics across the Demographic and Health Survey, Multi-Indicator Cluster Survey and Service Provision Assessments to help monitor gender-related barriers in immunisation delivery.
- The Gavi Monitoring and Learning (M&L) Plan draws upon a selected number of indicators measurable through publicly available sources. It facilitates the monitoring of health system and immunisation strengthening activities as well as outlining what works to reach zero-dose children.

- 9. Building country capacity through Technical Assistance support**, outlining how technical assistance support will contribute to building country capacity
- 10. Sustainability of new vaccine introductions**, outlining how the country will ensure the financial sustainability of a new vaccine introduction.
- 11. Supplementary documents**, any other supplementary documents that would support the information contained in this concept note, as well as evidence to demonstrate the prerequisites are met if applying for one off support or vaccine catalytic financing.
- 12. Signatures of relevant parties**, including the Ministry of Health and, where relevant, the Ministry of Education and implementing partners. Implementing partner signatures can be substituted by formal meeting minutes, e.g. official ICC meeting minutes to document when it was discussed with partners.

## 2. Costed Workplan

**Reminder:** as per Table 1, the Costed Workplan should be completed as follows for the different support elements:

<b>Technical Assistance</b>	Required
<b>One-off support for vaccine introduction costs</b>	Required
<b>Vaccine Catalytic Financing</b>	<u>Not</u> required

The Costed Workplan should be presented using the excel template in Tab "2. Costed Workplan" as part of the file "MICs\_NVI support combined\_Request detail\_vF"

Please note that Tab "2a. Costed Workplan Summary" will auto populate based on the inputs into Tab 2.

**Costed Workplan:** For each antigen (to be specified in column A), each activity identified in part 3 of the Concept Note (see above) should be listed in the Costed Workplan in column B. Then, for each activity, the following information should be provided in the subsequent columns:

- Which of the MICs Approach Intermediate Outcomes the activity primarily contributes

towards. Please see the [MICs Approach Theory of Change and associated narrative](#) for more details (*column C*)<sup>11</sup>

- Support type (Technical Assistance or one-off support) (*column D*)
- Alignment with a New Vaccine Introduction Plan (*column E*)
  - *Note that requests for One-off support must align with activities included in the New Vaccine Introduction plan.*
- A breakdown of the Activity into its different components, noting that that each sub-activity will need to be classified according to the Cost Framework Cost Category and Cost Sub-Category (see tab “Cost Framework” for details). Please add as many lines as required to break down each activity. Further breakdown can be given in a separate tab is needed (*column F*)
  - *Please repeat columns A to E for each sub-activity – this ensures that the ‘summary’ tab will autocomplete. i.e. Columns A to E of Activity 1 will be repeated for each sub activity row 1.1, 1.2, 1.3 etc.*
- Anticipated output for each sub-activity (*column G*)
- Implementing partner (e.g. WHO, UNICEF etc) or MoH. (*column H*)
- High level timing for the activity (please mark an ‘x’ in the relevant cell) (*columns I-N*)
- Cost Category and Cost Sub-Category for each sub-activity (see tab “Cost Framework” for details) (*columns O-P*)
- The budget (unit price and quantity (or number of FTE)) and timeline (*columns R-X*).
  - *The ‘totals’ will auto calculate based on the inputs*
- Budget assumptions, unit cost justifications and explanations, e.g. how the costs for a training course were calculated, job title of relevant staff and/or consultants, proportion of staff/consultant’s time dedicated to this activity, etc. Budget assumptions, unit cost justifications and explanations must be given to explain how the unit costs were derived. Where standard costs are applied, e.g., per diems, allowances, mileage rates, supporting national policy documentation should be provided. Further information can be submitted as a separate attachment to provide additional detail with reference made to these documents in this column. Supplementary worksheets can also be used if necessary (*column AD*)

**It is only necessary to include activities in the costed workplan which are being proposed to Gavi for funding.** Where complementary/supporting activities are taking place, funded from other sources (including domestic resources), please note these activities in the part 4 of the Concept Note.

At the bottom of the Costed Workplan, please complete rows for **Programme Administration costs**, with one row per implementing partner. All columns except columns C, E, and G are required. Note that these are not expected to exceed 7-8% of the total budget.

<sup>11</sup> Please note the intermediate outcomes for "sustainable access to PCV, rotavirus and HPV vaccines" is not featured in the drop down menu of the request detail template. This outcome speaks to Gavi's efforts to improve the enabling environment for sustainable pricing, including through collaboration with partners such as UNICEF and PAHO. Further, the intermediate outcome for "Routine immunisation services restored and reinforced to catch up missed children" is also not included as this is intermediate outcome is not supported by this support modality



### 3. A 'Dose Request' for Vaccine Catalytic Financing

**Note:** Countries should not prepare requests for Vaccine Catalytic Financing unless this has been agreed with Gavi in advance. Countries are strongly encouraged to work with their Gavi Senior Country Manager (SCM) to determine if Vaccine Catalytic Financing is an appropriate tool to support a successful new vaccine introduction. Please contact your Senior Country Manager for more information

**Reminder:** as per Table 1, the 'Dose Request' should be completed as follows for the different support elements:

<b>Technical Assistance</b>	Not required
<b>One-off support for vaccine introduction costs</b>	Not required
<b>Vaccine Catalytic Financing</b>	<b>Required</b>

The 'Dose Request' for Vaccine Catalytic Financing should be presented using the excel template in Tab "Dose Request for VCF", part of "MICs\_NVI support combined\_Request detail\_vF".

Countries can request Vaccine Catalytic Financing for doses for half of the first single-age target cohort of up to three new vaccine introductions of PCV, Rotavirus or HPV. The sheet should be completed with the following information for each vaccine:

- For which vaccine the VCF is being requested
- Which vaccine presentation the country plans to introduce
  - Countries may themselves determine which vaccine product to purchase providing the product of choice has received WHO Pre-Qualification
- How many total doses are required for a complete course of the vaccine
- Wastage rate for the vaccine and specific vaccine presentation. Please refer to the [WHO Vaccine Wastage Rates Calculator](#) for the standard wastage rates to be applied.
- The age of the target cohort for the new vaccine introduction (age in year). Note that for HPV, Gavi will only provide Vaccine Catalytic Financing for a single age cohort of girls aged between 9 to 14 years.
- Population size of this cohort (or for HPV how many girls are in this cohort), the year for which this data is presented (e.g. 2023). and the data source for this figure, including a link to a publicly available source where possible. Note that the data used should accord, where possible, with the year of introduction.
- **The number of doses being requested will auto-populate.**
- The preferred vaccine delivery date, noting that this cannot be guaranteed and shipment planning will be done in coordination with the procurement agency (UNICEF SD or PAHO RF)
- The expected date of introduction
- Number of instalments the country would like this award over (i.e. one or two). Note that the total amount of the award is the same regardless of the number of instalments.

The sheet should also be completed with information regarding:

- The required number and type of syringes
- The required number and type of safety boxes



Note that Gavi approval will be given for a set number of doses, not a financial envelope. The doses will be procured via a Gavi approved procurement partner. The cost of associated freight and any other costs, e.g. the procurement agency handling fee, will be calculated by the procurement agency directly. The procurement agency handling fee will be covered by Gavi. Shipment planning will be done in coordination with the procurement agency (PAHO or UNICEF). Please be aware that safe injection equipment shipment requires up to 5 months lead time, and shipment schedules should be planned accordingly.

#### 4. Accountability Framework

**Reminder:** as per Table 1, the Accountability Framework should be completed as follows for the different support elements:

<b>Technical Assistance</b>	<b>Required: Sections 1, 2 and 3 only</b>
<b>One-off support for vaccine introduction costs</b>	<b>Required: Sections 1, 2 and 3 only</b>
<b>Vaccine Catalytic Financing</b>	Not required at application stage <sup>12</sup>

The Accountability Framework should be presented using the excel template in the Tab “Accountability Framework” as part of the file “MICs\_NVI support combined\_Request detail\_vF”.

Countries and partners are expected to monitor performance and progress throughout the grant implementation period. The Accountability Framework presented in Tab “Accountability Framework” of the excel file is intended to help facilitate this process and is a **required element** of the funding request.

As well as supporting countries to monitor and learn throughout implementation of the programme, Gavi will use these data as part of the MICs Learning Agenda to better understand which investments are contributing to progress on the MICs objectives and how.

The Accountability Framework contains three sections:

- **Outputs:** Please populate this section with the Outputs listed in Column C of the Costed Workplan and indicators against which these will be measured. An example of an output indicator may include: *Costed implementation plan for introduction of new vaccines available; Percent of districts where civil society organisations conducted community awareness or mobilisation sessions; Percent of supportive supervision sessions conducted*. Each indicator should be assigned a corresponding target value.
- **Activities:** Please populate this section with the activities in the Costed Workplan. Over time, progress in implementation will be monitored by indicating whether activities are not started, in progress, or complete. If an activity is at risk (i.e., off track from the planned completion date), then it should be marked as such.
- **Doses administered:** [For recipients of VCF only] Following introduction of the new vaccine, recipients of Vaccine Catalytic Financing will be asked to report the number of doses administered from the beginning of the new vaccine introduction for a period of 12 or 24 months, depending on whether the VCF is received in 1 or 2 instalments.

<sup>12</sup> Countries will be required to complete section 4 for reporting purposes post-introduction

- **Budget:** The budget execution (use) rate will be monitored, disaggregated by staff/consultancy costs and activity costs. A corresponding target value should be assigned. Please note that the target should cumulatively add to 100% by the end of the grant period, assuming all Gavi funds are utilised.

#### **Reporting requirements:**

- **Reporting requirements for grant periods of at least one year:** Countries and partners will be expected to update the Accountability Framework and share it with Gavi every 6 months. An annual review will be required, for which countries and partners will be asked to complete a brief narrative template with reflections on outcomes and lessons learnt in addition to the updated Accountability Framework. Remaining disbursements will be dependent on successful completion of annual reporting requirements. At the end of the grant period, countries and partners will be asked to submit a final accountability framework alongside a final narrative template.
- **Reporting requirements for grant periods of less than one year:** Countries and partners will be expected to update the Accountability Framework and share it with Gavi 6 months into grant implementation. At the end of the grant period, countries and partners will be asked to submit a final accountability framework alongside a final narrative template with reflections on outcomes and lessons learnt. If the grant period is less than 6 months, no interim submission of the Accountability Framework will be required.
- **Post-introduction evaluations:** Countries introducing a new vaccine with Gavi support (Technical Assistance, One-off Costs, and/or Vaccine Catalytic Financing) will be required to conduct a post-introduction evaluation. The evaluation report must be shared with Gavi within one year of the new vaccine introduction.

**Outside of these formal reporting processes, it is expected that countries and partners engage with the relevant Senior Country Manager between reporting milestones to discuss progress, challenges, etc.**

#### **Finally, remember:**

- Do not hesitate to contact your Senior Country Manager for support at any time.
- Final country Support Requests must be formally submitted by email to [proposals@gavi.org](mailto:proposals@gavi.org) copying the relevant Senior Country Manager
- Please note that Support Requests for One-Off Vaccine Introduction Costs and Vaccine Catalytic Financing are subject to review by the IRC. Submissions to the IRC are subject to application deadlines. More information, including application deadlines, can be found here: <https://www.gavi.org/our-support/irc>