

Independent review considerations for new applications

This document outlines the aspects to be considered by the independent reviewers during the review of a country's request for new Gavi support (i.e. vaccine support; Health System Strengthening (HSS); and Cold Chain Equipment Optimisation Platform (CCEOP) support).

The points below are intended to facilitate the review and guide discussions between the independent reviewers and country stakeholders, if applicable. They should be adapted to the country context and the type(s) of support being requested. The outcomes of the review are captured in the IRC country report.

1. Robustness of the current immunisation and health programme

1.1. Coverage and equity situation: Sufficiency and appropriateness of focus on areas of low coverage or high inequity (relative to geographic, socioeconomic, cultural, gender or marginalised populations/zones)

Key areas, groups or populations and their challenges

- Has there been a clear prioritization of target geographies and/or socio-economic segments, anchored in a rigorous analysis of the coverage & equity situation (including both absolute numbers and percentage coverage), based on quantitative and qualitative data?
- Have the root causes, barriers, and/or bottlenecks for non- or partial-vaccination (drop-outs between PENTA1/3 and MCV1/MCV2) in those specific geographies or populations been presented and prioritized? E.g. have gender-related barriers¹ to immunisation been identified and addressed with mitigating strategies based on local context?
- Do the proposed supply and/or demand-side interventions address the specific, critical barriers to prioritized low coverage areas and/or underserved populations (i.e. supply chain; community engagement or demand generation; data availability, quality, and use; leadership, management, and coordination; and gender-related barriers), and are the interventions sufficiently tailored to the needs/contexts of those areas/populations?

Lessons learned, best practices or new interventions to accelerate progress

- Has the country adequately reflected past learning from implementation experience (e.g. joint appraisal) and best practice in describing the approach to improve the coverage and equity situation? To what extent have these been adequately incorporated for planning the future investments?
- Has the country built on experience from previous campaigns to reach consistently missed children? Have any changes been made based on lessons and achievements from previous campaigns to strengthen routine coverage?

For guidance on Gavi's core principles and requirements, refer to *section 2* of the « application guidelines » found here: <http://www.gavi.org/support/process/apply/>

1.2. PSR only: Review of implementation progress (replaces Joint Appraisal for current year)

Performance of existing Gavi support

- To what extent were the previously approved targets achieved?
- To what extent are the associated implementation challenges, as discussed during previous joint appraisals, recent EPI reviews (or similar), or any previous country evaluations (e.g. country HSS end of grant evaluations and Full Country Evaluations reports) being addressed?

¹ Gender-related barriers are obstacles (for access and use of health services) that are related to social and cultural norms about men's and women's roles. Women tend to be the primary caretakers of children, but sometimes lack the decision-making power and resources to access or use available health services.

Leadership, Management, and Financing

- Is there any evidence that programme, vaccine stock or financial management bottlenecks will materially impact the country's capacity to deliver on its objectives? (Based on evidence taken from previous Programme Capacity Assessments (PCA), programme audits and other sources)
- Overall, to what extent does the country have (or is clearly working towards having) the staff, structures, capabilities, processes and tools to manage its immunisation programme? This is particularly important the closer a country moves towards the accelerated transition phase.
- How does the requested Gavi support assist the country in increasing its leadership and management capacity?
- For **transitioning countries**: Does the country have the necessary expertise, experience and access to the right information to procure high-quality vaccines at appropriate prices?
- Was the country able to develop its annual operational plan? To what extent are the country's annual operational plans aligned to micro-plans? Was the immunisation programme budget developed on the basis of robust information about the cost of inputs and availability of funding (both from the government and donors)?
- Can the country produce a medium-term plan, an annual operational budget/workplan, and micro-plans?
- Are there any gaps between funds needed for the adequate operation of the immunisation programme (including for vaccine procurement and service delivery) and the resources available? If so, how does the government intend to address any funding gaps? How predictable are the sources of funding for the immunisation programme?
- Are there any bottlenecks or delays in the disbursement of funds (e.g. to the service delivery level) that negatively affect the timely functioning of the immunisation programme? Has the programme historically been able to absorb and execute the funding allocated to it?
- To what extent can the country adequately track and report on immunisation funding flows?

2. Coordination, transparency and alignment

Integration and alignment

- Overall, comment on how well Gavi's future contributions are aligned to the country's current national health plan, national M&E framework, other multi-year immunisation plan (e.g. cMYP) in terms of timelines, objectives, and key activities.
- Comment on the complementarity and coherence of Gavi support with other domestic or partner support
- To what extent are the different elements of the immunisation programme, particularly those supported by Gavi, integrated with/build on routine national systems and processes, where appropriate and necessary? Please comment on the extent to which there exists duplicative systems (e.g. data, supply chains, etc.), the rationale provided and complementarity of Gavi-supported systems with these duplicative partner-funded or national systems.

Functionality of country governance mechanism

- To what extent is the Coordination Forum (ICC/HSCC or equivalent body) functional/ active in providing strategic direction, oversight and transparency of the EPI programme (at minimum), of Gavi investments?
- To what extent is the Coordination Forum representative of a range of relevant stakeholders that are involved in the country health and immunisation sector (government, key donors, partners, key implementers, CSOs)?
- Does the Coordination Forum adhere to basic governance practices, including developing and sharing a formal TOR and meeting minutes, and adhering to the quorum in meetings?
- Has the Coordination Forum been adequately involved in the development of the request, including providing clear oversight and coordination with clear outcomes and endorsement?

- Does the country have technical capacity to advise the EPI on new vaccine introductions (e.g. have a functional NITAG)? If not, to what extent does the country have plans to establish one?

3. PSR only: Health Systems Strengthening (HSS) support – Programming of financial support

Appropriateness of proposed key activities to contribute to objectives

- To what extent do the proposed objectives (and the focus therein through key activities) reflect the findings from the situation analysis?
- Do the proposed interventions reflect best, current, and evidence-based practices and lessons learned from other relevant contexts?
- To what extent are the proposed interventions consistent with the Gavi's [Programming Guidance](#) on the critical areas that are common bottlenecks to improving equitable immunisation coverage? (Linking back to the bottlenecks identified in *section 1.1*)
- Do the proposed interventions adequately address any programme, vaccine stock or financial management bottlenecks that may impact the country's capacity to deliver on its objectives? (Linking back to the identified challenges in *section 1.2*)
- For the purposes of tailoring the budget, is enough detail provided in the PSR objectives narrative? It is important that the objectives are clearly expressed in order for Gavi to review subsequent year detailed budget activities and determine their alignment with the original application objectives
- If a transition assessment is available, how aligned are the objectives and the planned activities with the findings and recommendations from the transition assessment and the transition plan?

Optimal sequencing of interventions

- Does the support requested sufficiently consider the appropriate sequencing of interventions needed to sustainably improve immunisation coverage and equity? In particular, consider how the proposed investments align with Gavi's overall HSIS² approach:
 - Countries which are in earlier stages of Gavi's transition framework (e.g. low-income countries) are encouraged to prioritise systemic, long-term change (e.g. redesigning data systems or supply chains)
 - Countries in later stages of transition, particularly those in or expected to soon enter the accelerated transition phase, are encouraged to focus on investments with relatively shorter timeframes or ones where systemic change is urgently needed prior to transition (e.g. building capacity to procure vaccines at appropriate prices)

Appropriateness of proposed indicators (for HSS)

- Are the proposed tailored indicators and their targets, appropriate and sufficient to monitor and assess the results chain? Is there a realistic and logical flow from the requested support to the proposed indicators and targets?
- Are the proposed tailored indicators also taking into account the priority zones and populations targeted by the activities?
- Are the proposed targets reasonable in light of past performance?

Financing-related considerations

- Based on information available with regards to financial management and absorptive capacity, is there any evidence that financial management arrangements and plans for HSS are insufficient for a smooth transition out of Gavi support (e.g. do financial management arrangements require considerable external support). If so, comment on additional investment needs

² More on Gavi's Health System and Immunisation Strengthening (HSIS) framework can be found here: <http://www.gavi.org/support/hss/>

- If the support requested includes recurrent costs (particularly salaries/top-ups, costs such as maintenance, ongoing training, outreach, microplanning, or additional supplies), is there a plan for the government to increasingly cover and sustain these costs?
- Are these plans feasible given the country's past performance in mobilising additional resources?

Contribution of requested technical assistance (TA) to the capacity of the immunisation programme

- Has the country outlined technical assistance needs?
- Is the technical assistance requested for the upcoming year relevant to supporting the overall performance of the grants and EPI program? Specifically, how does it support the strategic objectives of HSS investments?
- Do the TA needs requested via HSS support complement TA support provided via the Partners Engagement Framework (PEF)?
- Does the TA support requested address recommendations from the Programme Capacity Assessment (identified in *section 1.2*), if available?

For guidance on Gavi's support for HSS, refer to *section 3* of the « application guidelines » found here: <http://www.gavi.org/support/process/apply/hss/>

4. Vaccine support: Prioritisation and implementation feasibility of new vaccine support requested

4.1. Strategic considerations (for all vaccines)

Strategic planning

- Are the new vaccine introductions and/or campaigns aligned with the national health documents (e.g. included in the cMYP)?
- Are there any critical steps to take prior to implementation (i.e. planned introduction or campaign)?

For PSR only

- Is the prioritisation (i.e. in terms of timelines) across the requested vaccine support appropriate? Is it based on sound analyses of country capacity, disease epidemiology and burden?
- Are introduction activities aligned with HSS programming, if applicable?
- Are introductions and campaigns adequately spaced over time (e.g. short interval between catch-up campaigns and routine introduction, intervals between preventive campaigns)?
- If a country is not currently eligible for a future planned vaccine introduction and/or campaign: Is it reasonable to assume the country is likely to meet the eligibility requirements (see [How to request new Gavi support](#)) prior to the indicated date for vaccine implementation?

Programmatic feasibility

- Comment on the country's justification for vaccine introduction or requesting campaign support, especially in view of its disease burden.
- In undertaking a critical assessment of the Plan of Action (PoA)/ New Vaccine Introduction plan (NVIP) and related detailed budget, does the country demonstrate adequate planning in terms of activities and timelines in order to ensure readiness for the vaccine introduction and/or campaign?
- Does the NVIP/PoA or other supporting document reflect cold chain capacity considerations? Is there anticipated sufficient cold chain capacity to accommodate the vaccine and/or are there EVM improvement milestones that are critical for the feasibility of specific introductions?
- Are the immunisation targets (number of beneficiaries) realistic and are they adjusted according to the delivery plans (e.g. if introduction will occur half-way through the year)?

Financial feasibility

- Do the activity plans and budgets have justifiable unit costs, a logical flow of activities, and link activities with outputs and objectives?
- Do budgets for financial support take into considerations all possible savings (i.e. leveraged any complementarities and synergies across Gavi's portfolio of support, including PEF TA, if applicable)?
- Has the country adequately considered the projected co-financing requirements and how they will be met (as demonstrated by the calculated projections and ICC sign-off)? Note that Measles / Measles Rubella follow-up campaigns require co-financing from 2018 onwards
- What are the sources of co-financing (government or other donor)? How predictable are they and what is the likelihood that these will be available to meet future co-financing obligations?
- If the country has recently defaulted on its co-financing obligations, what steps have been taken to mitigate the likelihood of further defaults?
- Have the funds needed to meet the co-financing obligations for the first year of this vaccine request already been budgeted for in the national budget? If not, how will this will be achieved?

4.2. Vaccine-specific considerations for each new vaccine support

4.2.1. Human papillomavirus (HPV) vaccine applications

Stakeholder workshop

- Has the country conducted a stakeholder meeting? If yes, were the outcomes of this meeting well incorporated to inform the implementation questions with regards to the delivery strategy, social mobilisation etc.

Target group

- Has the country chosen the routine cohort based on a single year of age or single grade in school within target age established by WHO?
- Has the country in the first year of introduction chosen a multi-age cohort for HPV vaccination based on SAGE (WHO) 2016 recommendations within target age group (9-14)? Has the country identified the routine cohort (e.g. 9 or 10-year-old)?
- Comment on the annual total (routine + multi-cohort) number of girls to be vaccinated by year.
- Comment on the appropriateness and justification of the age-grade groups selected and in particular the likely ability to reach these populations (routine and multi-cohort) to ensure high coverage, cost-effectiveness and sustainability.

Delivery strategy

- Comment on the appropriateness of the selected strategy (school-based, facility based, community outreach, mixed or other for vaccine delivery. In particular, assess the feasibility, coverage, acceptability and sustainability (e.g. integration with other existing programmes - routine delivery and/or school programmes)) of the delivery strategy.
- Comment on the proposed strategies to reach girls who missed vaccination, out of school girls, hard to reach, marginalised girls and the multi-cohort population.
- Regional Profile: Comment on the appropriateness of the delivery strategy vis-a-vis the district(s) choice taking into account topography, size (in population terms), access, demographics (in school, out of school girls), urban/rural.
 - Has the country specified whether they will use the same delivery strategy nationally or will the delivery strategies be adapted at the district level based on the aforementioned district profile (e.g. more efforts towards community vaccination in regions with high out of school girl population)?

Training, community sensitisation & mobilisation plans and evaluation

- Comment on plans for community sensitisation and mobilisation, in particular challenges identified and measures to address them
- Comment on the communication plan in addressing different audiences for communication like health worker, teacher, parents, community leaders etc.
- Does the country have a crisis communication plan to address the spread of rumours which can threaten the acceptability of a HPV vaccination programme?

Assessment of adolescent health interventions

- Comment on whether the country has explored the potential opportunity for integration between the adolescent health interventions and HPV vaccination. Kindly note, however, that the IRC recommendation for vaccine introduction should not be contingent on the country's decision to integrate HPV with other adolescent health interventions

4.2.2. Measles and Measles-Rubella vaccines applications

M and MR campaign requests

- Comment on the adequacy of the **justification** for conducting the campaign.
- Comment to what extent the country captures the key features of measles (and/or rubella) and immunity gaps based on: a) **immunisation coverage** and b) **disease epidemiology**.
- Comment on how the PoA follows the guidance provided in the **WHO SIA Planning and Implementation Guide** in terms of activities, timelines and tools (e.g. use of SIA readiness assessment tool, rapid convenience monitoring, mop-up vaccination, and post-campaign coverage survey).
- Has the country built on lessons learned from previous routine introductions and/or campaigns to provide evidence that it can achieve **high immunisation coverage during the campaign**? Are strategies that will be used to improve MCV coverage in hard to reach areas and underserved populations (particularly zero and one dose children), as well as other relevant target populations (e.g. urban slums, remote communities, migrant and/or refugee populations) described?
- Comment to what extent the country describes how **campaign activities will be used to reinforce routine immunisation and service delivery**.
- Is the proposed **budget based on the correct target population** and are the **operational costs aligned with the proposed service delivery strategies and within the expected range for the main op cost categories**? Are the costs well justified? Are the unit costs clear? Is the post campaign coverage survey budgeted for (funded by Gavi or another source)?
- Comment on the country's comprehensive **long term measles and rubella planning and budgeting**, provided as part of its cMYP or cMYP addendum (or measles and rubella strategic plan). If the country is not yet financing the measles component of MCV1, does the country provide evidence that it can meet the requirement to be self-financing from government funds from 2018 onwards, as a decision recorded in ICC minutes and a signed letter from MoH and MoF?

M and MR routine requests

- For MR applications, to what extent does the NVIP reflect **WHO guidance on the introduction of new vaccines**³? In particular, comment on the following:
 - revised immunisation schedule showing the age for MR vaccination;
 - plan for replacing Measles with Measles-Rubella, including the timing of the switch;
 - how the routine introduction will be used to reinforce routine immunisation and service delivery.
- For MCV2 applications (M or MR), to what extent does the NVIP reflect WHO guidance on introducing a second dose of MCV in the routine immunisation schedule⁴? In particular, comment on the following:

³ http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/

⁴ http://apps.who.int/iris/bitstream/10665/85900/1/WHO_IVB_13.03_eng.pdf

- revised immunisation schedule showing the age for MCV1 and MCV2 vaccination;
- whether immunisation policy has or will be changed in order to accommodate immunisation of children >12 months with MCV1 (and other antigens);
- plans to achieve high MCV2 routine coverage and maintain or increase MCV1 vaccine coverage (e.g. advocacy and social mobilisation activities, etc.);
- how the routine introduction will be used to reinforce routine immunisation and service delivery;
- plans to establish a second year of life immunisation platform, with integrated activities?
- Is the proposed **budget based on the correct target population**? Are the costs well justified? Are the unit costs clear?
- Comment on the country's comprehensive **long term measles and rubella planning and budgeting**, provided as part of its cMYP or cMYP addendum (or measles and rubella strategic plan). If the country is not yet financing the measles component of MCV1, does the country provide evidence that it can meet the requirement to be self-financing from government funds from 2018 onwards, as a decision recorded in ICC minutes and a signed letter from MoH and MoF?

4.2.3. Meningitis A (MenA) vaccine applications

- Has the country considered linkages or synergies with other possible interventions e.g, joint introduction with MCV2; or activities to increase coverage of YF, MCV1 or MCV 2
- Did the country include considerations for training health-care workers on vaccine co-administration practices and/or multi-dose vial handling, if applicable?
- For countries that have not introduced to RI have they considered an integrated request (one that includes both mass campaigns and routine)
- Comment on the extent to which the country's campaign activities contribute to strengthening routine immunisation. Is the necessary evidence acceptable?
- Do requests for campaigns correspond to the country's epidemiology, and are they targeted to areas in need?
- Is the chosen target population supported by epidemiological (or other) data?

For catch up campaign

- Do the list of areas/districts/zones and targets compare with the initial SIA (i.e. in the same areas where SIA were previously conducted)? If not, is epidemiological evidence provided for the new areas not covered by mass campaigns; does the evidence support the new areas?

For mass preventive campaign

- Has the country provided information on the coverage from the most recent campaigns (of any vaccine, up to 3)?
- Have the lessons learned from previous campaigns use of SIA readiness assessment tool, risk assessments, been taken into consideration to ensure high quality campaigns?
- Does the country plan to introduce Men A into their routine infant vaccination schedule and when?
- Does the op cost budget include key campaign activities including an independent post-campaign evaluation plan?
- Has the country considered using controlled temperature chain (CTC)?

4.2.4. PCV applications

- Is the country adopting the WHO-recommended immunisation schedule?
- Did the country include considerations for training health-care workers on vaccine co-administration practices?
- Did the country develop a comprehensive and integrated strategy alongside other interventions?

- Is the country planning to train health-workers on multi-dose vial handling for preservative-free vaccine?

4.2.5. Typhoid vaccine applications (available May 2018)

4.2.6. Yellow Fever vaccine applications

- Does the country have any strategies to improve YF coverage in hard to reach areas and underserved populations for both routine and campaigns?
- Has the country highlighted any potential linkages with other interventions/integrations, including either MenA, MCV1 or MCV2?
- Did the country include considerations for training health-care workers on vaccine co-administration practices and/or multi-dose vial handling, if applicable?
- If the country is requesting support for preventative mass campaigns, and has not yet introduced YF into the routine EPI, has it provided evidence committing to introduce into routine immunisation within 6 to 12 months after conducting the campaigns?
- Have the lessons learned from previous campaigns, use of SIA readiness assessment tool, risk assessments, been taken into consideration to ensure high quality campaigns?
- Comment on the extent to which the country's campaign activities contribute to strengthening routine immunisation. Is the necessary evidence acceptable?
- Do requests for campaigns correspond to the country's epidemiology, and are they targeted to areas in need?
- Is the chosen target population supported by epidemiological (or other) data?

4.3. Appropriateness of proposed indicators (for each vaccine support requested)

- Are the proposed tailored indicators and their targets, appropriate and sufficient to monitor and assess the results chain? Is there a realistic and logical flow from the requested support to the proposed indicators and targets?
- Are the proposed targets reasonable in light of past performance? If the quality of administrative coverage data is poor, are there other appropriate intermediate indicators closely associated with coverage that would allow for tracking of progress on improving coverage and equity?

4.4. Contribution of requested technical assistance (TA)

- Is the technical assistance requested for the upcoming year relevant to support the strategic objectives of the vaccine introduction, RI or data quality strengthening, or campaign?

For guidance on Gavi's support for vaccines, refer to *section 4* of the «application guidelines» found here: <http://www.gavi.org/support/process/apply/vaccine/>

5. Supply chain (CCEOP) applications

- Does the proposed timeframe align with the country's strategic deployment plan? Is it realistic?
- Does the country clearly describe the CCE situation in the country?
- Is the specific, quantified need for rehabilitation and expansion of the country's CCE well justified (new vaccine introductions, expanding cold chain reach, population growth, and equipment beyond useful life)?
- Is the rationale for the rehabilitation and expansion of the CCE aligned and supported by a CCE inventory and facility segmentation, CCE rehabilitation and expansion plan, EVM Assessment report and health system bottleneck analysis?
- Does the objective link to broader Gavi (and other partners) support in the country (e.g., HSS, NVS) & cMYP, most recent EVM assessment, etc
- Is it clearly described how the objective(s) and key activities will contribute to addressing SC bottlenecks?

- Is it well described how the proposed CCE rehabilitation and expansion plan will impact the system's design and contribute to the efficiency/effectiveness of the supply chain (accounting for the commissioning and decommissioning of CCE)?
- Has the country described how the routine maintenance and repairs will be predictably financed and their implementation ensured?
- Has the country provided indicators that will track the contribution of the CCE to vaccination programme goals in achieving coverage and equity and strengthening the supply chain?
- Are the indicators provided aligned to the National M&E Plan, if existing?
- Is the country's joint investment secured? Is the source of the joint investment provided?

For guidance on Gavi's support for CCEOP, refer to *section 5* of the «application guidelines» found here: <http://www.gavi.org/support/process/apply/cceop/>