

Annex B: Additional detail on updates to the mechanism and simulated ranking of country applications

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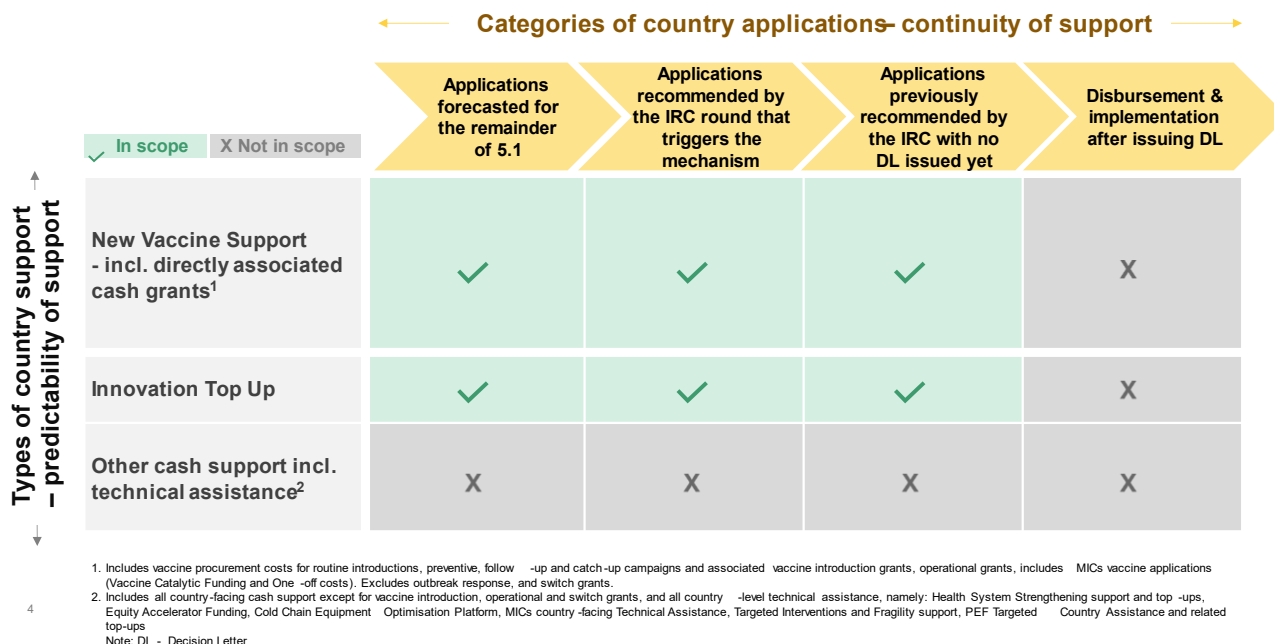
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1. Summary of key changes to the prioritisation mechanism

		Existing mechanism	Proposed mechanism
Principles		Objectivity, transparency, feasibility	Existing principles + simplicity, continuity of support and predictability of support
Scope	Category of application	Applications from countries recommended for approval by the IRC on a round-by-round basis	Informed by 'continuity of support' principle: protect ongoing country programmes focusing prioritisation on country applications not yet binding including: <ol style="list-style-type: none"> i. Applications forecasted (for 2025) ii. Applications recommended for approval in an IRC round iii. Applications previously IRC recommended and with no decision letter issued yet
	Types of support	Restricted to New Vaccine Support applications from countries	Informed by 'predictability of support' principle: protect cash grants with communicated ceilings (incl. HSS, EAF, TCA) and focus prioritisation on: <ol style="list-style-type: none"> i. New Vaccine Support applications¹ ii. Cash grants with no communicated ceilings (Innovation Top Up)
Objectives		<ul style="list-style-type: none"> • Maximise health impact (30%) • Maximise value for money (30%) • Reinforce financial sustainability of immunisation programmes (25%) • Support countries with the greatest needs (15%) • Promote equitable distribution of Gavi's resources among countries (each country can only prioritise one application) 	<p><i>Changes to objective names to better reflect intention</i></p> <p>No change:</p> <ul style="list-style-type: none"> • Maximise value for money (30%) <p>Refined indicators:</p> <ul style="list-style-type: none"> • Minimise loss of health impact (30%) • Safeguard financial sustainability of programmes (30%) • Support countries with greatest needs indicator moved under 'financial sustainability' objective • Maintain equitable access to vaccine (10%) <p>New:</p> <ul style="list-style-type: none"> • Minimise risk of disruptive future outbreaks and impact on global health security (qualitative assessment) • Minimise risks to market health (qualitative assessment)

1. Includes preventive, follow up, catch up campaigns, MICs vaccines) and related cash grants (VIGs & Ops). Exclude outbreak response, switch grants; incl. Applications linked for epidemiological reasons to be assessed together

2. Overview of the scope of the updated prioritisation mechanism for Gavi 5.1



3. Implications of the operationalisation of the priority mechanism

- **Impact on Gavi's mission indicators and SG targets:** The prioritisation mechanism will need to result in some country applications being left unfunded for the remainder of the 5.1 strategic period leading to missed opportunities for public health impact and risks of missing Gavi's mission indicators and SG targets (including 'must wins'). The mechanism manages this risk as much as possible through the design of its scope, objectives and indicators.
- **Country impact:** Certain countries will need to postpone new programmes, which will require additional resources in country to update plans, or to implement costly outbreak response activities in the case of preventative campaigns being deprioritised.
- **Inter-country equity:** Whilst the mechanism takes into account previous vaccine introductions, there is a risk that the prioritised country applications will be dominated by high cost, high impact applications which restricts how many countries will be able to benefit from the available funding.
- **Middle Income Countries (MICs):** There is a risk that currently supported MICs will fall out of Gavi support in 6.0¹ and could miss an opportunity to introduce a high impact vaccine. Additionally, the methodology for the value for money indicator does not take into account the costs to Gavi alone for MICs

¹ Current forecast of countries that may fall out of support of the Catalytic phase (ex 'MICs-approach') in 6.0 includes pending validation in 2025: Armenia, Azerbaijan, Cuba, Georgia, Indonesia, Moldova, Algeria, Belize, El Salvador, Iran. This does not apply to inactivated polio vaccine (IPV) support for Former Gavi-eligible countries, which is currently supported by Gavi irrespective of a country's transition status.

programmes (which is a one-time investment for vaccines and auxiliaries equivalent to 50% of the first cohort per introduction, with the rest funded by the country), but the full costs to Gavi and country, per the methodology, which has a proportionally negative impact on the calculation of value for money for MICs.

- **Market health:** The screen for market health risks will be of a qualitative nature such that those presenting highest market risk are potentially spared. Nevertheless, depending on the extent of deprioritisation needed, there will likely be some deprioritisations that present significant market impact (either short- or long-term) if demand does not materialise as expected.
- **Malaria:** The currently available modelling does not take into consideration the "indirect effects" of malaria vaccine on non-malaria causes of death, for example, on secondary bacterial infections, which are estimated to be large. As an example, the MVIP evaluation found that malaria vaccine introduction resulted in a 13% reduction in all-cause child mortality. By not accounting for the contribution of malaria infection to other causes of child death, the current estimates would underestimate the health impact and value for money of the malaria vaccine. The Secretariat will work with partners and modellers to ensure the modelling is representative of the impact of malaria vaccine and update the scoring accordingly.

4. Proposed changes to indicators and application of indicators

Table 1: Objectives and recommended changes to indicators and weightings

Objective	Current Mechanism Indicator	Weight	Proposed changes for 5.1	Weight
Ranking objectives				
SG 1: Minimise loss of health impact	<ul style="list-style-type: none"> • <i>Routine Immunisation:</i> Ratio of future deaths averted to total population from the first five years of vaccination • <i>Campaigns:</i> Ratio of future deaths averted to total population, from year of vaccination. In case of subnational campaigns, calculate the proportion of the targeted populations 	30%	Future deaths averted per fully vaccinated person	30%
SG 1: Maximise value for money	<ul style="list-style-type: none"> • Cost per future death averted • Calculated as Weighted Average Price per vaccine course divided by future deaths averted per fully vaccinated person 	30%	No change	30%
SG 2: Maintain equitable access to vaccines	This objective was defined as "Ensure equitable allocation of resources between countries" and measured through the criteria of funding only 1 application per country per IRC round	n/a	Percentage of Gavi supported vaccines that a country has introduced relative to the total the number of vaccines the country is eligible to receive	10%
SG 3: Safeguard financial sustainability of programmes	<ul style="list-style-type: none"> • Co-financing performance for Gavi supported vaccines in the last five years measured by # of years in default 	25%	<ul style="list-style-type: none"> • Co-financing performance measured by country's ability to meet co-financing obligations in the last five years by 31 Dec or the fiscal year as agreed with the country 	30%

	<ul style="list-style-type: none"> • % of spending on vaccines used in routine immunisation financed with Government funds • Encompasses objective previously called 'support countries with greatest need' measured by gross national income per capita 		<ul style="list-style-type: none"> • Gross national income per capita 	
Non-ranking objectives				
SG 1: Minimise risks of outbreaks & strengthen global health security	n/a	n/a	Qualitative criterion used to identify significant risks in cases where potential for outbreaks is assessed as 'high' based on e.g. Global Health Security risk, Country outbreak risk and Vaccination impact on disease with epidemic potential	
SG 4: Minimise risks to market health	n/a	n/a	Qualitative criterion used to identify significant risks in cases where impact on market is assessed as 'high' based on e.g., the three Demand Health criteria of the Board-approved Healthy Market Framework	

a) Updated indicator: Minimise loss of health impact

- Previously this indicator was computed as future deaths averted in the first five years of the programme divided by total population, for routine introductions, and future deaths averted from campaign activity divided by total population, for campaigns.
- In the past several years, the Alliance has tended to quantify vaccine impact as future deaths averted per fully vaccinated person (FVP). For example, this was used extensively in the recent Vaccine Investment Strategy to compare the impact of different vaccines.
- Deaths averted per FVP is a more parsimonious and balanced way to make comparison across applications. It treats routine introductions and campaigns similarly and does not require accurate forecasting of the timing of vaccination activities across years, e.g., for phased campaigns. It also does not penalise targeted vaccination strategies, for example subnational targeting of the malaria vaccine, for which the original indicator divided (subnational) deaths averted by total country population size.

b) Updated indicator: Ensure equitable use of vaccines

- Previously this objective was defined as 'ensure equitable allocation of resources between countries' and measured through the criteria of funding only 1 application per country per IRC round.
- Objective updated to '**ensure equitable use of vaccines**', measured by the percentage of Gavi supported vaccines that a country has introduced relative to the total the number of vaccines the country is eligible to receive. The change to the indicator aims to promote inter-country equity in access to Gavi vaccine funding and control for the timing factor whereby countries applying for introductions late in the strategic period are potentially penalised, meaning that the indicator has been updated to take into consideration any prior

introductions a country made. Countries that have fewer introductions of Gavi-supported vaccines relevant to the country would score higher.

c) Updated indicators: Safeguard financial sustainability of programmes

- Previously this objective was measured by the number of years a country was in default in the past five years as well as the percentage of spending on vaccines used in routine immunisation financed with Government funds.
- The indicators to measure financial sustainability were updated based on current context. No countries have defaulted over the past five years meaning that another indicator was required, with country ability to meet co-financing obligations on time serving as an alternative. The second indicator that considers government spending on health was removed due to lack of robust and reliable data. Countries which have received waivers from the co-financing obligations will not be penalised under this indicator.
- Additionally, this objective now also encompasses the objective called 'support countries with greatest need' which was measured by gross national income per capita. The indicator has not changed.

d) New objective: Minimise risks to market health

- Addition of **qualitative assessment** for '**minimise risks to market health**': used to flag significant risks in cases where impact on market is considered 'high'. Gavi is frequently faced with specific country introduction or switch decisions that have outsized bearing on the vaccine market in question. Assessment of high risks is based on the three Demand Health criteria of the Healthy Market Framework² (i.e. materialisation of demand, predictability of demand, and balanced demand of appropriate products & timely uptake of new innovative products). An example of a 'high' risk to market health would be when a deprioritisation is predicted to lead to supplier exit/supplier precarity, leading to decreased overall supply security or to price increases for all other countries associated with lack of demand materialisation. See Table 1 below.

Table 1: Definition of sub-indicators for 'minimise risks to market health' objective

Sub-indicators	Definition	Thresholds		
		Low risk	Medium risk	High risk
Materialisation of demand	The degree to which country introductions and campaigns materialise vs. expectations	High demand materialisation vs. expectations of manufacturers	Acceptable demand materialisation vs. expectations of manufacturers	Very low demand materialisation vs. expectations of manufacturers
Predictability of demand	The degree to which both the quantity and timing of demand can be accurately predicted and sustained by countries	High predictability of demand	Acceptable predictability of demand	Very low predictability of demand

² The updated Healthy Market Framework was approved by the Board in June 2021 as part of the Market Shaping Strategy

Balanced demand of appropriate products & timely uptake of new innovative products	The degree to which country product choices are data-driven, value-based; leading to balanced demand for appropriate products & timely uptake of new innovative products	Good balance of demand for appropriate products and good uptake of new innovative products	Acceptable balance of demand for appropriate products and acceptable uptake of new innovative products	Poor balance of demand for appropriate products and delayed uptake of new innovative products
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- **New objective: Minimise risk of disruptive future outbreaks and impact on global health security**
- Addition of **qualitative assessment for ‘Minimise risk of disruptive future outbreak and impact on global health security’**: used to flag significant risks in cases where potential for outbreaks is considered ‘high’ in the near future (i.e. following year). This addition reflects the Alliance’s commitment to outbreak, epidemic and pandemic response and low risk appetite for outbreaks³. Assessment of high risks is based on the three criteria: a) global health security risk, b) country outbreak imminent risk, and c) vaccination impact on disease epidemic potential. The relevant definitions will be further defined in the Standard Operating Procedures. An example of ‘high’ risk impact could include where not implementing a programme is likely to have outsized public health impact such as leading to an outbreak due delayed activities resulting in large immunity gaps, and/or is likely to spill over to create epidemics in other countries. See table 2 below.

Table 2: Definition of sub-indicators for ‘minimise risks of outbreaks and strengthen global health security’ objective

Sub-indicators	Definition	Thresholds		
		Low risk	Medium risk	High risk
Global Health Security	Per: • Disease virulence, transmissibility, and availability of MCMs per WHO 2024 R&D Blueprint • Alignment with Global Agendas (SDGs, IA2030, Disease)	<ul style="list-style-type: none"> • Considered as low PHEIC risk by R&D Blueprint (e.g., HPV) • Low disease transmissibility (e.g., Rabies) • Available and accessible medical countermeasures (e.g., DTP) 	<ul style="list-style-type: none"> • Considered as medium PHEIC risk by R&D Blueprint • Available but not accessible medical countermeasures • Global Agenda (e.g. measles elimination) 	<ul style="list-style-type: none"> • Consider as high PHEIC risk by R&D Blueprint (e.g., Ebola) • Currently graded as PHEIC (e.g., Polio) or Pandemic (e.g., Cholera) • Global Agenda (e.g., Polio eradication)
Country Outbreak Risk	Per: • Burden of disease in the country • Country vaccination coverage • Disease basic rep. number (R0) and herd immunity threshold. • Disease Case Fatality Ratio (CFR)	<ul style="list-style-type: none"> • The disease is endemic with small expected susceptible pop (e.g., Rotavirus). • Vaccination coverage ≥ herd protection levels. • Low R0 and CFR (~ R0<2 and CFR<1%) 	<ul style="list-style-type: none"> • The disease is partially endemic, with mixed level of immunity within the population. • Vaccination coverage is near herd protection levels, but gaps remain. • High R0 or high CFR, but not both 	<ul style="list-style-type: none"> • Disease is not endemic and low expected seroprevalence (large susceptible pop.) or large immunity gaps (e.g., YF) • Country vaccination coverage below herd protection. • High R0 and CFR (~ R0> 2 and CFR > 1%)

³ See Gavi Risk Appetite Statement December 2023

Vaccination Impact on Disease Epidemic Potential	<p>Per:</p> <ul style="list-style-type: none"> Vaccination activity proposed. Risk of triggering outbreak support requests to Gavi if the vaccination activity is not conducted. Vaccine characteristics (duration of protection, doses required, implementation feasibility) 	<ul style="list-style-type: none"> Little or no ability to prevent future epidemics/ outbreaks, including those as a result of climate change No significant risk of outbreak requests without vaccination. Short-term immunity or multiple doses required. 	<ul style="list-style-type: none"> Reduce frequency/ size/ other impact of epidemics/ outbreaks, including those as a result of climate change Potential for outbreak requests if vaccination gaps persist Moderate immunity duration, typically requiring 2-3 doses 	<ul style="list-style-type: none"> Vaccination can prevent future epidemics/outbreaks, including those as a result of climate change Not implementing the proposed vaccination activity will lead to outbreak response request to Gavi Long-lasting immunity, 1-2 doses required
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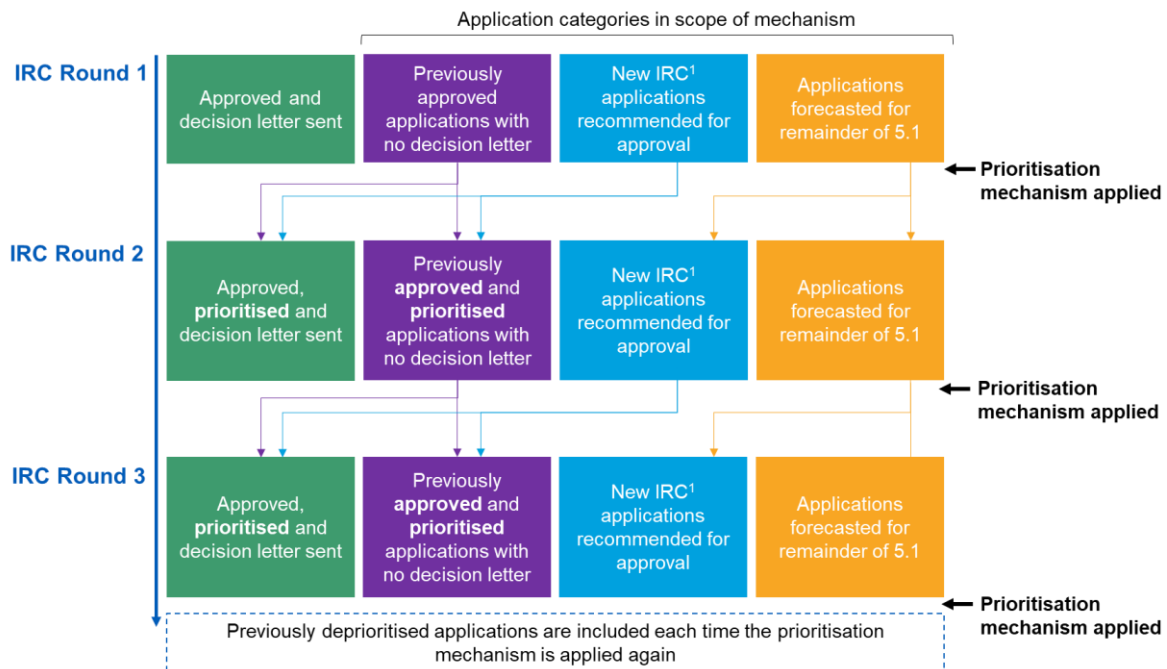
5. Rationale for proposed changes to weighting

The weighting of the objectives was updated to accommodate new objectives. Minimise loss of health impact and Maximise value for money retain equal weighting as per the current mechanism. Supporting lower income countries and financial sustainability was considered equally important. Inter-country equity was seen as an important outcome of the process in consultations with country representatives and was thus also weighted in the ranking the updated mechanism.

Table 3: Changes to weighting

Related Strategic Goal	Objective	Current mechanism weight	Proposed new weight
SG1	Minimise loss of health impact	30%	30%
	Maximise value for money	30%	30%
	Minimise risk of disruptive future outbreaks and impact on global health security	n/a	Qualitative criteria
SG2	Maintain equitable access to vaccines	n/a	10%
SG3	Safeguard financial sustainability of programmes	25% (as well as 15% for support countries with greatest need)	30%
SG4	Minimise risks to market health	n/a	Qualitative criteria

6. Detailed flow of country applications through Gavi's funding cycle over IRC rounds



7. Inclusion of country priority parameters

The proposal is to allow countries to trade-off prioritised applications for those predicted to not be prioritised, if that better reflects their priorities. For example: Country X has a US\$ 100 million application for a measles-rubella (MR) campaign that is prioritised, and a US\$ 40 million application for an HPV introduction and US\$ 50 million hepatitis B birth dose introduction that have been deprioritised based on the ranking. Country X can decide to fund the HPV and / or hepatitis B birth dose introductions instead of the MR application. Funding of the deprioritised application(s) in lieu of prioritised one(s) would be possible if the value of the former does not exceed that of the prioritised application(s).