

Annex B: Paragraphs referenced in decision point (b) on the MICs Approach, as amended by discussions at the PPC

4. MICs Approach engagement¹

- 4.1 **This section presents how best to continue to deliver against the two MICs Approach objectives for the remainder of Gavi 5.0**, fine-tuning the approach already approved by elaborating on the support to prevent and mitigate backsliding and bringing additional emphasis to the objective to drive the sustainable introduction of new vaccines². This does not mean losing sight of any potential future ambitions but takes a pragmatic view on what can be achieved in the time available, alongside recognising that the MICs Approach is, as a whole, a learning agenda.
- 4.2 **The approach responds to the needs expressed by countries. It is results-orientated, designed to work in partnership with countries toward a shared objective of fostering sustainable and equitable immunisation programmes.** It works to leverage the capacities in MICs, supporting countries to have a greater impact with available domestic resources and to catalyse new resources for immunisation while not creating dependencies. **The approach draws on Gavi's comparative advantages and leverages the Alliance's strengths to address key barriers to new vaccine introductions and challenges to sustainable and equitable immunisation programmes.** It presents the interventions determined to have the greatest impact with the resources available whilst recognising ongoing challenges. Support is **targeted** and **catalytic**, combining **targeted country-facing support** with investments that work to affect **system-level change where multiple countries face similar challenges**. The MICs Approach works with a **clear focus on sustainability** across all investments, working not only with Ministries of Health but with all relevant stakeholders, including Ministries of Finance and subnational authorities. As part of the learning agenda, it also seeks to find complementarity between the two MICs Approach objectives with all investments clearly aligned to the MICs ToC (see Appendix 3).
- 4.3 The Approach is first comprised of three **Foundational Building Blocks**, designed to **address country challenges** in all countries eligible under the MICs Approach by sustainably addressing shared barriers to new vaccine introductions, the drivers of backsliding, and risks to immunisation programme sustainability including ensuring sufficient and sustainable health financing, thus working towards both MICs Approach objectives. The building blocks reflect the MICs Approach's ambition to find new ways to deliver sustainable results by generating momentum and building and strengthening the enabling environment. Efforts will be tailored to country needs and will include **country advocacy to galvanise political commitment** for sustainable and equitable RI across MICs, using the convening power of the Alliance to bring together immunisation leaders and promote evidence and best practice on immunisation

¹ The MICs Approach does not currently include support for COVID-19 vaccines. Future potential support on COVID-19 vaccines is currently a topic for PPC and Board discussion.

² Introducing these vaccines not only saves lives through vaccination but also contributes to wider global health priorities, e.g. reducing antimicrobial resistance with the introduction of PCV.

and to reach zero-dose children³. Commitments will be turned into action with the support of **multi-country and regional technical assistance initiatives** delivered by relevant core and expanded partners (including CSOs, academic institutions, and the private sector)⁴. Finally, existing capacities in MICs will be amplified through **action-orientated peer-to-peer knowledge sharing platforms**⁵ where countries will be supported to share best practices and lessons learnt on sustaining high-performing immunisation programmes and introducing new vaccines. Platforms will also provide a channel to share Alliance innovations.

4.4 The Foundational Building Blocks are complemented by **responsive and catalytic country-specific tools which will work at country level**. Bespoke investments will respond to country needs, supporting former-Gavi countries to mitigate backsliding in vaccine coverage and supporting countries eligible under the MICs Approach that are yet to introduce PCV, rotavirus and HPV vaccines to sustainably and equitably introduce these key missing vaccines.

a) **Support to Mitigate Backsliding in former-Gavi countries:** Direct support to mitigate backsliding via “Targeted Interventions”, taking zero-dose as an entry point, will continue to be available to former-Gavi countries facing significant and sustained backsliding, **restoring RI services by identifying and sustainably reaching zero-dose children** by tailoring approaches to local needs. Approved in December 2020 as a temporary intervention, it is proposed to continue this support for former-Gavi countries given the significant ongoing country need⁶. ‘Targeted Interventions’ support’ consists of direct funding to countries to sustainably reach zero-dose children alongside technical assistance support to in-country partners to assist the government to achieve this objective. This support will also be provided through co-investments with the World Bank. Support to Angola has already been recommended for approval by the Independent Review Committee (IRC) and proposals are in development with Indonesia, Honduras, and Bolivia. The Secretariat continues to closely monitor coverage data for former-Gavi countries using both formal WUENIC data and country-level admin data to identify additional former-Gavi countries that may need this support in the coming years.

b) **Vaccine Introduction Assistance:** To drive sustainable and equitable new vaccine introductions, countries could access **Technical Assistance (TA)** via the right mix of core and expanded partners, including CSOs and academic institutions⁷. Countries could also access **flexible support to cover one-off introduction costs** that are either traditionally unfunded or difficult to fund⁸. There would be no entitlement to support, and countries

³ Activities will target multiple countries via e.g., WHA (World Health Assembly), UNGA (United Nations General Assembly), AU (African Union), as well as focussing on specific countries where relevant.

⁴ e.g. identifying sustainable financing for immunisation, regulatory harmonisation and strengthening technical advisory bodies

⁵ e.g. the Linked Immunisation Action Network

⁶ Support to prevent backsliding will continue to be primarily delivered through Technical Assistance from core and expanded partners as part of the Foundational Building Blocks

⁷ e.g. plans for sustainable financing of vaccines, decision making and product choice; demand forecasts; equitable, gender-responsive introduction plans; licensing; post-introduction evaluations

⁸ e.g. Communication campaigns to reach historically missed communities

would need to demonstrate how they will sustain a successful new vaccine introduction. Any support would be one-off, time limited, and complementary to other funding initiatives.

- c) **Sustainable access to new vaccines:** Taking a collaborative approach to working with UNICEF Supply Division (SD), PAHO Revolving Fund (RF) and manufacturers, Gavi will create **a more favourable environment for countries eligible under the MICs approach by supporting sustainable access to vaccines**, including a pathway to sustainable pricing⁹. Supporting demand pooling for these countries is one tool that will mitigate the risks of short-term unpredictable demand, and Gavi is exploring working in partnership with UNICEF SD to support an adapted version of the Vaccine Independence Initiative (VII) as an innovative financing mechanism¹⁰ to support eligible MICs, leveraging Gavi's financing capabilities at no risk to Gavi to enable longer-term demand certainty and reduce barriers for countries to participate in pooled procurement mechanisms. Gavi is also exploring options for collaboration with the PAHO RF. The Secretariat proposes to also make available **Vaccine Catalytic Financing (VCF)** for the cost of half the first birth (or target) cohort. This support model has been used previously in countries by Gavi and has proven highly effective in driving the sustainable introduction of new vaccines¹¹, and has the potential for an impressive return on investment: every US\$ 1 invested in VCF could catalyse US\$ 1-5 of domestic vaccine financing by 2025 and US\$ 11-15 by 2030, equivalent of up to US\$ 1 billion if Gavi invests up to US\$ 70 million. Together, these interventions will help accelerate new vaccine introductions by addressing issues that prevent manufacturers offering more sustainable vaccine prices for these countries¹². By developing new market opportunities, manufacturers will also benefit from these interventions and will thus be encouraged to commit to a single, low sustainable price for countries eligible under the MICs Approach¹³.

- 4.5 **The MICs Approach and Vaccine Markets:** The MICs Approach seeks to catalyse new vaccine introductions through multiple levers, one of which is the **creation of conditions favourable to manufacturers offering sustainable pricing** for countries eligible for the MICs Approach. Gavi continues to engage with manufacturers on the objectives of the MICs Approach and has already initiated a working group with PAHO RF and UNICEF SD to identify common areas of interest and collaborative approaches to pricing and markets for supporting new vaccine introductions. Every Gavi-supported antigen is subject to an in-depth market shaping strategy (known as a "roadmap"). The roadmap process considers overall market dynamics, of which business in MICs is usually a key element. Any potential vaccine market implications of the MICs

⁹ Whilst this work may have implications for global market health for PCV, RV, HPV vaccines as new MIC markets open up, we expect any impact would not be significant. While the MICs Approach will not invest in regional manufacturing directly, some efforts may have a beneficial impact.

¹⁰ Previously referred to as an Innovative Financing Facility

¹¹ e.g. Bolivia, Honduras, Guyana, and Sri Lanka each introduced and sustained HPV vaccines following this support. In Timor-Leste a similar approach garnered firm introduction commitments

¹² In supporting new vaccine introductions, Gavi will not disrupt relationships between countries and manufacturers for established vaccination programmes, nor set price caps or price targets.

¹³ Former-Gavi countries continue to benefit from existing, time-limited price commitments at least for the duration of 5.0 based on the specific terms and duration of each price commitment.

Approach, including on pricing for Gavi-eligible countries, will be captured through this roadmap process for the antigens in question, with the Gavi Market Shaping and MICs Approach teams already working in close collaboration. It is also noted that prices for PCV, rotavirus and HPV for Gavi-eligible countries are already locked in through at least 2025 thus negating any near-to-medium term impact on prices for Gavi-eligible countries and allowing for any course correction should there be any indication that these prices are at risk as a result of the MICs Approach (although this is not expected). Additionally, manufacturer price-freeze commitments for former-Gavi countries are in place from some manufacturers through at least 2025 for the antigens in question. Gavi will continue to monitor and assess the best strategy to ensure access to sustainable prices for former-Gavi countries after the price commitments end.

5. Ambitions for the MICs Approach

- 5.1 Developed in consultation with partners and teams across the Secretariat, the **Theory of Change** for the MICs Approach (Appendix 3) has since been revised to reflect the above proposals and will continue to provide the framework for all the Approach's investments, setting out a clear path to achieving its objectives. The **Learning Agenda** (Appendix 5) also continues to accompany the MICs Approach, informing understanding of disruption and recovery in MICs and helping to assess the impact of interventions.
- 5.2 There are two **Gavi Strategic Goals (SG) aligned with the objectives of the MICs Approach**. The Indicator and Target for SG3.2 ("Preventing backsliding in former-Gavi countries") was approved by the Gavi Board in December 2020. The proposed Indicator for SG3.3, specific to new vaccine introductions, was awaiting further elaboration of the MICs Approach and is now proposed as the "number of new vaccine introductions (PCV, rotavirus, HPV) in former- and never-Gavi countries eligible under the MICs Approach" (Appendix 3). Whilst there is no target against the SG3.3 indicator, reflecting that the MICs Approach is a learning agenda, an increasing number of new vaccine introductions is expected.
- 5.3 **The MICs Approach has a clear set of ambitions that reflect its focus on results.** These desired outcomes also contribute towards the Immunization Agenda 2030 goals. Based on the approach outlined above, the Secretariat believes the MICs Approach could have the following impact by the end of Gavi 5.0¹⁴:
 - a) Restore routine immunisation coverage in former-Gavi countries:
 - i) 90% of countries with >90% pre-COVID DTP3 coverage¹⁵ restore coverage back above this threshold;
 - ii) Remaining countries arrest the decline in DTP3 coverage and begin an upward trajectory;
 - b) Reduce the number of zero-dose children in former-Gavi countries by

¹⁴ Ambitions (a) and (b) do not include countries considered as fragile

¹⁵ 12 former-Gavi countries had >90% pre-COVID DTP3 coverage

230,000 children, equivalent to 15%¹⁶ of the zero-dose population in these countries; and,

- c) Sustainably and equitably introduce 8-10 new vaccines in countries eligible under the MICs Approach, reaching 4 million-6 million children/adolescents with PCV, rotavirus and/or HPV vaccines.

5.4 **Achieving this impact implies remaining flexible in how available tools are deployed to best meet country needs.** But this flexibility will be balanced by closely monitoring the contribution of investments towards our ambition via a **comprehensive measurement framework**. Data on indicators defined against the intermediate and long-term outcomes in the ToC will be collected to monitor progress, inform programme adaptation, elucidate which investments have contributed to progress and how, and will be reported to the PPC and Board. Reports will also include updates on country-level activities and any observed impacts on vaccine market dynamics.

6. Proposed indicative allocation of resources

6.1 **All investments under the MICs Approach are from the approved envelope of US\$ 281 million.** The Board approved this envelope to avoid diverting resources from Gavi-eligible countries who have high needs. In June 2020 the Board approved US\$ 20 million to work with former-Gavi countries to mitigate backsliding. That work has been fully integrated into the MICs Approach and the Secretariat proposes to also integrate these budgets, bringing the total budget to US\$ 301 million. To date, approximately US\$ 12 million of the MICs Approach Budget has been allocated, reflecting both the proactive decision to phase the implementation of the MICs Approach and the extremely stretched bandwidth of both countries and the Secretariat in recent years as a result of the pandemic. However, country appetite to engage on the MICs Approach agenda has significantly accelerated in recent months and already proposals worth an additional US\$ 20 million are expected to be finalised in the coming months with more in the pipeline, indicating an encouraging and significant uptick in implementation. **In keeping with the MICs Approach's focus on results and the subsequent need to tailor interventions to respond to country contexts, exact distribution of the remaining budget will depend heavily on country needs,** for example the amount spent on flexible one-off support for new vaccine introductions will depend on country need for such support. Hence the Secretariat does not propose a precise budget breakdown nor country-specific allocations. **All investments will however be dedicated to strengthening the sustainability of immunisation programmes,** with approximately one third of the budget dedicated to preventing and mitigating backsliding and two-thirds dedicated to supporting the introduction of new vaccines (recognising that over twice as many countries are eligible for this type of support). **Across both these objectives, the vast majority (~75%) will be spent at country-level** with the remaining ~25% being spent on multi-country initiatives through the Foundational Building Blocks, supporting innovative financing mechanisms and secretariat staffing (see below). All investments under the MICs Approach will be highly targeted and guided by the MICs ToC,

¹⁶ Aligns with strategic goal to reduce zero-dose in Gavi-eligible countries by 5% per year during Gavi 5.0

only proceeding where there is real prospect to affect change. The MICs Approach is also highly catalytic in nature, amplifying the value of Gavi funding. Anticipated investments through the MICs Approach can already point to leveraging potentially significant additional funds for immunisation from the World Bank and Regional Development Banks, the GFF (Global Financing Facility), and domestic resources.

- 6.2 The Secretariat will require staff to implement the proposed MICs Approach and the budget for these resources will be ~3% of the total (~US\$ 9 million). Staff will be dedicated to country engagement, supporting engagements with core and expanded partners, sustainable access to vaccines, and the MICs Learning Agenda. The MICs Approach will also provide support for core and expanded partners, including CSOs¹⁷, primarily at country and regional level¹⁸. This cost will be met from within the approved envelope so as not to displace resources from Gavi-eligible countries¹⁹. **The Secretariat considers the unique nature of the MICs Approach, noting its defined budget envelope and the requirement to ensure that other teams within the Secretariat are not overly burdened, also warrants different internal processes and different decision-making pathways than those laid out in the Programme Funding Policy.** It is thus proposed that funding for 'Targeted Interventions' and 'flexible, one-off support' that will go directly to countries be reviewed by the IRC, as well as Vaccine Catalytic Financing support²⁰. Decisions for all other elements of support, including technical assistance for core and expanded partners and for Targeted Interventions support channelled via the World Bank, would be made by the DCEO or CEO reflecting both the lower risk to Gavi of these investments and the request to minimise the burden of the implementation of the MICs Approach on other Secretariat-wide processes.

Table: Indicative budget allocation

Intervention area		Range
Secretariat		3%
Foundational Building Blocks		8 - 11%
<ul style="list-style-type: none"> Advocacy to galvanise political commitment Regional and multi-country initiatives Peer-to-peer knowledge sharing platforms 		
Responsive and catalytic tools	Vaccine Introduction Assistance	13 - 20%
	<ul style="list-style-type: none"> Country-specific Technical Assistance Flexible, one-off support 	
	Sustainable Access to Vaccines	30 - 40%
	<ul style="list-style-type: none"> Innovative Financing Mechanism Vaccine Catalytic Financing 	
	Targeted Interventions to mitigate backsliding	18 - 25%
		Total: US\$ 301 million

¹⁷ Alongside Gavi's Civil Society and Community Engagement Approach, the MICs Approach promotes the role of CSOs in supporting sustainable and equitable immunisation programmes.

¹⁸ e.g. via multi-country initiatives and through country-specific technical assistance

¹⁹ These staffing needs were not included in the Gavi Organisational Review for this reason

²⁰ IRC review will be specifically tailored for these support modalities and will be lighter compared to core Gavi funding.