

**SUBJECT:** GAVI'S APPROACH TO ENGAGEMENT WITH FORMER AND NEVER-ELIGIBLE MIDDLE-INCOME COUNTRIES (MICS)

**Agenda item:** 09

**Category:** For Decision

## **Section A: Executive Summary**

### **Context**

In December 2020, the Gavi Board approved the Middle-Income Countries (MICs) Approach to address intra- and inter-country inequities in former- and select never-Gavi eligible countries. In view of the COVID-19 pandemic, the Board approved a phased implementation and requested that the Secretariat come back in June 2022 to elaborate on how best to continue to deliver against the MICs Approach objectives for the remainder of Gavi 5.0, alongside whether country eligibility should be expanded to include all never Gavi-eligible upper middle-income countries (UMICs) with gross national income (GNI) p.c. (per capita) under US\$ 6,000. In response to requests from the Programme and Policy Committee (PPC) and countries, the Secretariat also explored how Gavi could respond to the needs of fragile MICs.

### **Questions this paper addresses**

1. How best to continue to deliver the MICs Approach for the rest of Gavi 5.0
2. Whether to expand eligibility to include all UMICs under US\$ 6,000 GNI p.c
3. If Gavi should have a rules-based approach to supporting fragile MICs
4. If Venezuela should be treated as eligible under the MICs Approach

### **Conclusions**

This paper presents the PPC's recommendation to the Gavi Board on how best to continue to deliver the MICs Approach for the remainder of Gavi 5.0, maintaining the focus on preventing and mitigating backsliding and strengthening sustainable immunisation programmes whilst elaborating on how to drive sustainable new vaccine introductions. In discussions, the PPC confirmed key tenets of the MICs Approach, underscoring the importance of sustainability and of responding to country needs. The PPC agreed that now is not the right time to expand eligibility to include all UMICs under US\$ 6,000 GNI p.c. but rather to allow countries reclassified as lower-middle income countries (LMICs) due to falls in GNI to become eligible for the MICs Approach. This paper also presents the PPC's recommendation for a rules-based approach under which support could be provided to fragile eligible-MICs. Finally, following validation of the approach taken

by the Secretariat and additional UN data, the paper presents the PPC's recommendation to treat Venezuela as eligible under the MICs Approach.

## **Section B: Content**

### **1. Background**

- 1.1 **In June 2019 the Gavi Board recommended the Alliance institutionalise its support to former Gavi-eligible (hereafter “former-Gavi”) countries.** Whilst most former-Gavi countries successfully transition from Gavi support, some have gaps in programmatic capacities creating a risk of backsliding in vaccine coverage<sup>1</sup>. Besides jeopardising the legacy of Alliance investments, backsliding disproportionately impacts the most vulnerable, exacerbating intra-country inequities. Moreover, former-Gavi countries lag behind in introducing critical vaccines, presenting a threat to inter-country equity: of 19 former-Gavi countries, 6 are missing pneumococcal conjugate vaccine (PCV), 8 are missing rotavirus vaccine, and 9 are missing human papillomavirus (HPV) vaccine. Recognising these challenges, **the Board requested the Secretariat develop an approach to support former-Gavi countries to prevent backsliding in vaccine coverage and to introduce key missing vaccines.**
- 1.2 Despite higher immunisation investments on average, never Gavi-eligible (hereafter “never-Gavi”) countries with comparable income levels to former-Gavi countries similarly lag behind on key vaccine introductions: 71% of never-Gavi LMICs are missing PCV, rotavirus and/or HPV vaccines. In some countries these vaccines are available but only in the private sector, placing them out of reach for the poorest and most vulnerable. Given Gavi's goal to ‘leave no-one behind with immunisation’ and in the era of the Sustainable Development Goals, the Board considered these inter- and intra-country inequities impossible to ignore and **requested the Secretariat explore how select never-Gavi MICs could also be supported to introduce key missing vaccines by finding new ways to engage and catalyse domestic resources towards this shared objective.**
- 1.3 **Gavi's MICs Approach, approved by the Board in December 2020, addresses these key threats to inter- and intra-country equity by seeking to both prevent backsliding in vaccine coverage in former-Gavi countries and to drive the sustainable introduction of key missing vaccines in former and select never-Gavi countries.** The Board approved the initial country eligibility to include all former-Gavi countries, never-Gavi LMICs and IDA-eligible economies (hereafter “eligible-MICs”) and approved a US\$ 281 million budget for Gavi 5.0. The Board also recognised that the pandemic exacerbated the challenges facing former-Gavi countries: COVID-19 and the ensuing economic downturn increased both the risk and extent of backsliding, with average DTP3 coverage in former-Gavi countries declining by 5 percentage points and the zero-dose

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<sup>1</sup> Note that countries approaching transition are actively supported with transition planning via the Full Portfolio Planning (FPP) process.

population growing by 41% between 2019 and 2020. **The Board thus approved that the MICs Approach also provide support to mitigate backsliding in former-Gavi countries that had seen significant and sustained reductions in coverage levels.** Further recognising the pandemic's impact, the Board decided to phase the MICs Approach's implementation, initially focussing on preventing and mitigating backsliding in a select number of former-Gavi countries, building relationships with never-Gavi countries via COVAX, and developing the Theory of Change and Learning Agenda (see Appendix 1 for highlights of this work). Indeed the MICs Approach, as a whole, is recognised to be a learning agenda. Approval for the MICs Approach has only been given for Gavi 5.0, emphasising the need to learn what works when collaborating with eligible-MICs to achieve these shared objectives.

- 1.4 The Board asked the Secretariat return in June 2022 to elaborate on how best to continue delivering the MICs Approach for the remainder of Gavi 5.0, alongside whether to expand country eligibility to include upper middle-income countries (UMICs) under US\$ 6,000 GNI p.c. Following requests from the PPC and countries, the Secretariat also explored if and how Gavi could respond to the needs of fragile MICs. In May and June 2022, the PPC reviewed both the plans for continuing to deliver against the two MICs Approach's objectives and the Secretariat's proposal for a rules-based approach to respond to the needs of eligible-MICs facing situations of fragility, emergencies and displaced populations. **This paper presents the outcomes of these discussions for the Board's approval.**

## 2. Country eligibility for support under the MICs Approach<sup>2</sup>

- 2.1 Initial country eligibility for the MICs Approach was approved by the Board in December 2020 and included all former-Gavi countries, never-Gavi LMICs (i.e. those under ~US\$ 4,000 p.c. GNI) and IDA-eligible economies (see appendix 2 for the list of eligible-MICs). The PPC agreed that now was not the right time to expand country eligibility for the MICs Approach to also include all UMICs up to US\$ 6,000 p.c. GNI<sup>3</sup>, recognising the need to be pragmatic in the time left under Gavi 5.0. However the PPC did **recommend the Board approve updating the list of eligible-MICs in line with the latest and forthcoming GNI data<sup>4</sup>.**

## 3. The MICs Approach: Addressing inter- and intra-country inequities

- 3.1 **The MICs Approach seeks to address barriers that countries have identified as standing in the way of sustainable and equitable new vaccine introductions as well as the drivers of backsliding in vaccine coverage.** It is specifically designed to flexibly respond to the specific needs expressed by countries in recognition of the high level of heterogeneity in

<sup>2</sup> In this paper, "countries" is used to denote both countries and economies.

<sup>3</sup> Country eligibility for the MICs Approach already includes 10 IDA-eligible UMICs in recognition of their specific vulnerabilities.

<sup>4</sup> Countries will remain eligible for the duration of Gavi 5.0 given the long lead times for new vaccine introductions and the need for support predictability.

MIC contexts. Examples of the challenges identified by different eligible-MICs include: insufficient political commitment toward immunisation, waning confidence in and demand for vaccines, limited programmatic and institutional capacities, insufficient and unreliable domestic resources for immunisation, and unsustainable vaccine prices. **At its core, the MICs Approach is results-orientated, working in partnership with countries toward a shared objective of fostering sustainable and equitable immunisation programmes.** By combining support to address system-level challenges via multi-country initiatives with dedicated and flexible country-specific tools, the MICs Approach maintains a clear focus on sustainability by not creating dependencies but rather supporting countries to have both a greater impact with available domestic resources and to catalyse new resources for immunisation. See annex B for more details.

- 3.2 **The MICs Approach seeks to achieve explicit outcomes, reflecting its clear focus on results.** The Secretariat believes that, by December 2025, the MICs Approach will: prevent and mitigate backsliding in vaccine coverage in former-Gavi countries<sup>5</sup>; reduce the number of zero-dose children in former-Gavi countries by 230,000 children<sup>6</sup>; and sustainably and equitably introduce 8-10 new vaccines in eligible-MICs<sup>7</sup>. Progress against these outcomes in Gavi 5.0 will help determine if the MICs Approach should become a more integral part of Gavi’s model in Gavi 6.0. A **theory of change** sets out a path to achieving these outcomes and a **comprehensive measurement framework** will monitor progress. A **learning agenda** accompanies the MICs Approach, helping to inform its implementation and enabling any needed course correction (appendices 3 and 4). There are two **Gavi Strategic Goals** (SG) aligned with the MICs Approach. The indicator for SG3.2 “Preventing backsliding in former-Gavi countries” has already been approved and the indicator for SG3.3 is now proposed as the “Number of new vaccine introductions (PCV, rotavirus, HPV) in former- and never-Gavi countries eligible under the MICs Approach”<sup>8</sup>. Reports on the MICs Approach’s progress will be presented to the PPC and Board, including country-level activities and vaccine market developments as monitored through the antigen-specific market shaping roadmaps and collaborative dialogue with PAHO RF, UNICEF SD, and manufacturers<sup>9</sup>.
- 3.3 The Gavi Board approved US\$ 281 million for the MICs Approach in Gavi 5.0. The Board had previously, in June 2020, approved US\$ 20 million for work with former-Gavi countries to mitigate backsliding. This work has

<sup>5</sup> Specifically that 90% of former-Gavi countries with >90% pre-COVID DTP3 coverage restore coverage back above this threshold, and the remaining countries arrest the decline and begin an upward trajectory

<sup>6</sup> This is equivalent to 15% of the zero-dose population in these countries and aligns with strategic goal to reduce zero-dose in Gavi-eligible countries by 5% per year during Gavi 5.0

<sup>7</sup> These outcomes are aligned with goals set out in the Immunisation Agenda 2030 MICs Annex.

<sup>8</sup> See appendix 3. There is no target against indicator SG3.3 reflecting that the MICs Approach is a learning agenda. However, an increasing number of new vaccine introductions is expected.

<sup>9</sup> Note that it is not anticipated that supply or prices for Gavi-eligible countries will be impacted by the MICs Approach. Supply and pricing are already committed for these countries for the antigens in question through at least 2025, negating any near-to-medium term impact and allowing time for course correction in the interim should there be unintended adverse consequences.

been fully integrated into the MICs Approach and the **PPC recommends the Board approve also integrating these budgets, bringing the total to US\$ 301 million.** In keeping with the focus on results, the exact division of the budget will depend on country needs thus neither a precise breakdown nor country-specific envelopes are proposed, yet all investments will be dedicated to strengthening the sustainability of immunisation programmes with circa one-third of the budget focussed on preventing and mitigating backsliding and two-thirds budget on supporting new vaccine introductions<sup>10</sup>, recognising that over twice as many countries are eligible for this type of support. Across both objectives, the majority of the budget (~75%) will be spent at country-level. The MICs Approach is also highly catalytic in nature, amplifying the value of Gavi funding by leveraging additional resources. Secretariat staff, funded from the approved budget<sup>11</sup>, will be needed to implement the MICs Approach, accounting for ~3% of the total budget (~US\$ 9 million). Funding for core and expanded partners will also be provided.

- 3.4 **The unique nature of the MICs Approach, including its defined budget and the request to not overly divert resources from Gavi-eligible countries, merits tailored processes and decision-making pathways.** It is thus proposed that funding that will go directly to countries for “Targeted Interventions” and “flexible, one-off support” be reviewed by the IRC, as well as “Vaccine Catalytic Financing”<sup>12</sup>. Decisions for all other elements of support, including technical assistance for core and expanded partners and co-investments with the World Bank and other multilateral development banks, will 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.
- 3.5 **The PPC agreed with the overall plan for how to continue delivering the MICs Approach for the remainder of Gavi 5.0,** but underscored the importance of sustainability, including sustainable financing for immunisation, and emphasised that the MICs Approach must respond to country needs. The PPC also requested the Secretariat provide additional details on several elements of the MICs Approach including: “Targeted Interventions” support to mitigate backsliding in former-Gavi countries; work with UNICEF SD on an innovative financing mechanism; market shaping aspects of the MICs Approach; indicative MICs Approach budget allocations; and the rationale for the proposed funding approval pathways. The PPC also requested that reporting on the MICs Approach include updates on country-level activities and any observed impacts on vaccine market dynamics. **The MICs Approach, amended as per the requests of the PPC described above, is presented in Annex B and is recommended by the PPC for the Board’s approval.**

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<sup>10</sup> Support to fragile eligible-MICs is distinct from this but is not expected to significantly alter this balance

<sup>11</sup> These staffing needs were not included in the Gavi Organisational Review for this reason.

<sup>12</sup> IRC review will be specifically tailored for these support modalities and be lighter versus core Gavi funding.



#### 4. Responding to the needs of fragile eligible-MICs

- 4.1 The MICs Approach approved in December 2020 was not designed to respond to the needs of fragile eligible-MICs and so did not include support to help countries maintain critical routine immunisation programmes during times of crisis. When the Board reviewed and approved the MICs Approach, the PPC Chair reported that several **PPC members had suggested the Secretariat further explore how to work with fragile MICs**<sup>13</sup>. Since then, global events including conflict and economic crises have brought the challenges facing affected countries into alarming focus and several MICs experiencing such challenges have requested Gavi's support.
- 4.2 In response to these requests, and following feedback from the PPC in May 2022, the Secretariat has developed a **rules-based approach for providing dedicated support to eligible-MICs that face challenges caused by fragility, emergencies, and displaced persons**. Under this approach, eligible-MICs must meet three conditions to be considered for dedicated support to help maintain their routine immunisation programme:
- The country must fall within the classification for settings of chronic fragility, acute emergencies and/or hosting displaced populations as per Gavi's Fragility, Emergencies and Displaced Populations Policy<sup>14</sup>;
  - There must be an evidence-based demonstration of a time-limited need, against which Gavi is best placed to respond in line with the Alliance's comparative advantages; and,
  - Gavi's support remains time-limited, and the country gives a clear commitment to sustain funding for immunisation following the end of Gavi support, thereby assuring a clear exit strategy and avoiding the creation of dependencies in line with Gavi's development model<sup>15</sup>.
- 4.3 Time-limited support, determined on a case-by-case basis and channelled exclusively through partners, could include a portion of vaccine financing for existing routine vaccines, technical assistance, and potentially access to Gavi prices (where this could lead to savings and with the agreement of manufacturers). Any support would be funded from the MICs Approach budget, up to a ceiling of 25% of the total budget (i.e. up to ~US\$ 75 million), and would only be provided as a last resort. Whether the conditions have been met and the provision of any support will be approved by the CEO. The proposed approach ringfences potential support within clear boundaries that speak to Gavi's model and the Alliance's comparative advantages, whilst recognising that Gavi is not a humanitarian organisation. See annex C for more details. Noting that no eligible-MICs currently meet all the conditions set out above, **the PPC recommends the Board approve the rules-based approach to provide dedicated support to eligible-**

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<sup>13</sup> Board meeting, December 2020

<sup>14</sup> See Doc 07: Review of Fragility, Emergencies, Refugees Policy

<sup>15</sup> There is no 'standard' exit strategy but would include a commitment to sustainable vaccine financing to ensure Gavi support does not create dependencies. CSOs could have a key role in this process.

## MICs facing challenges caused by fragility, emergencies, and displaced persons.

- 4.4 The World Bank is unable to provide a 2020 income classification for **Venezuela**<sup>16</sup>. This is expected to also be the case for 2021. Venezuela is experiencing one of the worst economic crises ever seen and it is not possible to know if Venezuela is eligible for the MICs Approach or not. The only similar situation Gavi has faced was in 2016 when assessing if Syria was Gavi-eligible. Following the same process used then, the Secretariat reviewed IMF<sup>17</sup> and other data<sup>18</sup> and undertook analysis which indicated Venezuela is likely to have similar income levels as an LMIC. The Secretariat's methodology has been validated by the IMF Venezuela Country Team as requested by the PPC. Further, data recently published by the UN shows 2020 p.c. GNI to be US\$ 3,380<sup>19</sup>, well within the LMIC threshold<sup>20</sup>. This further confirms the Secretariat's analysis. Whilst the PPC is unable to determine if Venezuela is an LMIC, given the highly unusual lack of World Bank income classification and the exceptional circumstances facing the country and, by extension, the whole region<sup>21</sup>, **the PPC agreed, and recommends the Board agree, that Venezuela be treated as eligible for support under the MICs Approach**<sup>22</sup>. Venezuela would then also be eligible to be considered for dedicated fragility support, but this would only be provided if all three conditions are met.

### Section C: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

- a) **Approve** updating the list of lower middle income countries eligible for support under the MICs Approach in line with 2021, 2022 and 2023 World Bank GNI data released in 2022, 2023 and 2024 respectively;
- b) **Approve** the proposed intervention, secretariat resourcing, and funding approval pathways as per Annex B to Doc 09 as amended by discussions at the PPC;
- c) **Approve** extending the implementation time from until June 2022 to until the end of December 2025 for use of the US\$ 20 million for targeted support previously approved by the Board in June 2020 for former Gavi-eligible

<sup>16</sup> Venezuela is currently the only country without a World Bank income classification

<sup>17</sup> The IMF estimates that Venezuela's real GDP fell 35% in 2019 followed by a 30% decline in 2020. IMF estimates updated April 2022 [www.imf.org/en/Countries/VEN](http://www.imf.org/en/Countries/VEN)

<sup>18</sup> E.g. ENCOVI 2021 Survey of Living Conditions [www.proyectoencovi.com/encovi-2021](http://www.proyectoencovi.com/encovi-2021) and Knoema <https://knoema.com/atlas/Venezuela-Bolivarian-Republic-of>

<sup>19</sup> <https://unstats.un.org/unsd/snaama/CountryProfile> (select tab 'GNI')

<sup>20</sup> Economies with GNI per capita between US\$ 1,046 and US\$ 4,095

<sup>21</sup> See appendix 5 for more details on the situation in Venezuela

<sup>22</sup> Gavi will consider how to manage any future situations where there is a lack of GNI / income classification data from the World Bank to allow the CEO to take future eligibility decisions

countries;

- d) **Approve** the rules-based approach to supporting eligible MICs that meet the conditions to receive dedicated fragility support as outlined in Annex C to Doc 09.

Noting that a GNI classification is not available for Venezuela, and that there is a national and regional threat to immunisation coverage, and further to additional consultations with relevant partners on a best estimate of GNI

- e) **Agree** that Venezuela be treated as eligible under the MICs Approach.

### **Annexes**

**Annex A:** Implications/Anticipated impact

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

**Annex C:** Paragraphs referenced in decision point (d) on the rules under which support could be provided to fragile MICs

### **Additional information available on BoardEffect**

**Appendix 1:** Highlights of the work to date

**Appendix 2:** List of countries eligible for support under the MICs Approach as of 1 April 2022

**Appendix 3:** Updated MICs Approach Theory of Change, Narrative, Measurement Framework and Indicator Reference Sheets for SG3.2 and 3.3

**Appendix 4:** MICs Approach Learning Agenda

**Appendix 5:** Update on the situation in Venezuela