

SUBJECT: UPDATE ON DEVELOPMENT OF STRATEGY FOR MIDDLE-INCOME COUNTRIES (MICs)

Agenda item: 10

Category: For Information

Section A: Executive Summary

Context

In June 2019, the Board requested the Secretariat to develop an institutionalised approach for post-transition support to former Gavi-eligible countries and, in response to inter-country equity concerns, to also explore extending this approach to select never Gavi-eligible middle-income countries (MICs)¹. This paper presents an update to the Board on progress and the current thinking.

Questions this paper addresses

1. From the country perspective, what are the main barriers to immunisation programme sustainability and new vaccine introductions (NVIs)?
2. Based on these findings, what could Gavi's MICs approach include and how will it leverage the Alliance and wider partner efforts?

Conclusions

Barriers to NVIs and sustaining immunisation programmes are complex and interwoven. Countries perceive the sustainable financing of vaccines and operations and vaccine price as key issues alongside a lack of political will, restrictive procurement policies, inadequate data, and regulatory issues. Other challenges include limitations in decision-making, insufficient supply chain capacity and maintenance, and growing vaccine hesitancy. Manufacturers consider low political will and regulatory barriers to be the main bottlenecks to NVIs and emphasise the importance of addressing these alongside procurement support.

An MICs approach would be designed to prevent backsliding in former Gavi-eligible countries and to stimulate the sustainable introduction of key missing vaccines in former and never-Gavi eligible countries. Crucially, the approach would also be designed to both mobilise and maximise the efficiency of countries' domestic resourcing for immunisation. It could include three inter-linked and mutually reinforcing components to address these challenges: advocacy and political will building, targeted technical assistance, and an innovative financing facility to support procurement. Each component could be tailored to the different groups of countries. It would leverage the Alliance and wider partner initiatives including UNICEF Supply Division (SD), the WHO MICs Strategy, and existing

¹ Specifically, countries with a GNI p.c. under US\$ 4,000 and possibly countries up to US\$ 6,000 GNI p.c.

Global Fund relationships, and builds on the considerable existing capacities of MICs themselves.

Section B: Content

1. Introduction

- 1.1 In June 2019, the Board recommended that the Alliance's approach to former Gavi-eligible countries be institutionalised in Gavi 5.0. They requested that the Secretariat develop an approach with the objectives of introducing key missing vaccines and preventing backsliding in immunisation coverage levels post-transition. The Board considered it relevant to also explore how some elements of this approach could be expanded to some never Gavi-eligible MICs, with the main focus on NVIs, to address the inter-country equity challenge that is impossible to ignore in light of Gavi's ambitious goal of 'leaving no-one behind with immunisation'.
- 1.2 Following this decision, the Secretariat has been building a more nuanced picture of the potential risks of backsliding and the barriers to NVIs in MICs, and exploring how to leverage the Alliance's comparative advantages to address these. Through further analysis and consultation with key partners, former and never Gavi-eligible countries, and manufacturers, Gavi has been refining differentiated modalities of engagement to different groups of countries and investigating the feasibility of such an approach.

2. Country insights: what are the main barriers to immunisation programme sustainability and new vaccine introductions?

- 2.1 Former Gavi-eligible countries
- 2.2 Post-transition engagement with former Gavi-eligible countries aims to reduce the risk of stagnating or backsliding immunisation performance after transition. This objective is also enabled by the manufacturer price commitments (MPC) which guarantee time-limited access to Gavi-like vaccine prices for former Gavi-eligible countries, thereby mitigating the immediate post-transition risk of significant vaccine price increases. The success of this model is borne out by the data, which show that for most former Gavi-eligible countries DTP3 coverage is increasing or remains above 90%.² However, there are still some countries missing key vaccines: of the 16 former Gavi-eligible countries, four countries are missing pneumococcal vaccine (PCV), six are missing Rotavirus, and seven are missing human papillomavirus vaccine (HPV). Cuba and Indonesia are the only countries missing all three vaccines, mainly due to decisions on local vaccine manufacturing.
- 2.3 Consultations were held with former Gavi-eligible countries from EURO (WHO European Region), SEARO (WHO South-East Asia Region) and WPRO (WHO Western Pacific Region). These countries raised concerns

² The only instance of backsliding DTP3 coverage between 2016-2018 is Bolivia.

about **future financial sustainability** due to uncertainty on vaccine prices after the MPC ends, including for NVI. Countries requested support on this issue, both through continued access to attractive prices and potentially through catalytic co-financing of NVI. These concerns on sustainable financing and immunisation performance reinforce the need to institutionalise the MPC.

- 2.4 Another significant challenge raised by countries was **supply chain issues**, including vaccine storage, stock management, wastage, and cold chain capacity and maintenance as these former Gavi-eligible countries were not eligible for CCEOP support to improve their supply chains. Countries also reported confronting a growing issue of **vaccine hesitancy** and specifically asked for technical assistance to develop communication and social mobilisation strategies to address this. Quality **data management**, including for accurate forecasting of demand, was another ongoing requirement.
- 2.5 Finally, the need for continued **high-level government advocacy** with the Ministry of Health, and especially with the Ministry of Finance, was highlighted as a requirement to maintaining immunisation as a priority after transition and to ensure that it receives sufficient financing and attention.
- 2.6 Never Gavi-eligible countries
- 2.7 Consultations regarding never Gavi-eligible countries from AFRO (WHO African Region), EMRO (WHO Eastern Mediterranean Region), and WPRO surfaced several challenges affecting their ability to introduce new vaccines. **Vaccine price** and the resulting high burden this places on the budget was highlighted as a key barrier. Previous Gavi analysis has revealed that the price for vaccines in never Gavi-eligible MICs can be up to four times higher than the PAHO (Pan-American Health Organization) price³. Most of the countries consulted are using or willing to use UNICEF SD for pooled procurement, but some are unable to due to **country regulations** which requires tendering for the procurement of goods. Another restriction to using UNICEF SD is linked to prepayment requirements that in many countries are not allowed.
- 2.8 Other difficulties cited included **poor country management and decision-making capacity** (e.g. understaffing of the EPI or nascent NITAGs (National Immunization Technical Advisory Groups)) and a **lack of quality data** (e.g. an insufficient evidence-base for NVIs, suboptimal quantification and forecasting). **Weak logistics, poor supply chains and ageing equipment** (particularly in the cold chain), and **cumbersome regulatory processes** were other common issues highlighted by several countries. One critical gap identified in the AFRO region was **vaccine safety**, as MICs are the only countries in the continent not using the Auto-Disable (AD) syringe, which is of concern given the high HIV (human immunodeficiency viruses) rates. The universal utilisation of the AD syringe in Gavi countries

³ For PCV 1 dose, southern African MICs report paying US\$ 17-US\$ 20 per dose, and eastern European countries report paying US\$ 28-US\$ 50 per dose. The 2019 PAHO price for PCV is US\$ 12.85 (PCV-10) and \$US 14.50 (PCV-13).

is one of Gavi's early success stories. Many of these barriers could be seen to be related to a **lack of access to the latest technologies and approaches** and **lack of political will** for both current immunisation programmes and NVIs. Lastly, in line with the findings from former Gavi-eligible countries, never Gavi-eligible countries are also facing rising levels of **vaccine hesitancy**.

- 2.9 In light of these, MICs have been exploring ways to improve access to vaccines, including regional pooled procurement mechanisms. Several initiatives are currently being discussed, such as the ones spearheaded by EMRO, EURO, Small Island Developing States (SIDS), the Southern African Development Community (SADC) and others. Although some of these initiatives may address certain critical gaps such as increased political will and regulatory harmonisation, the proliferation of efforts poses a risk of demand fragmentation, which may be counter-productive for solving vaccine procurement issues. The Alliance presents an opportunity to offer a holistic approach, helping to address a multitude of bottlenecks including by augmenting UNICEF SD's existing procurement model. This directly contributes to WHO's Immunization Agenda 2030 (IA2030). The potential for the Alliance to help address these bottlenecks was welcomed.

3. The options for Gavi's MICs approach

- 3.1 The proposed MICs approach would be a component in the evolution of Gavi's engagement in the development continuum of countries, distinctly differentiating the scope and depth of support. Annex A presents a diagram of the proposed approach in the context of this continuum. The Secretariat's thinking on the proposed MICs approach is intrinsically linked to the ongoing Funding Policy Review to ensure alignment between these workstreams.⁴
- 3.2 Countries in scope include all former Gavi-eligible countries and never Gavi-eligible countries with a GNI up to US\$ 6,000 p.c. The Secretariat is exploring whether to include very small island states given their unique vulnerabilities (e.g. very low vaccine volumes linked to smaller population sizes can result in additional challenges). Other organisations recognise the unique context of small islands e.g. the World Bank's IDA (International Development Association) eligibility incorporates small islands in its criteria. Three high impact vaccines: PCV, Rotavirus and HPV, are currently in scope given the status of missed introductions, although given the supply constraints for HPV, the immediate focus will be on building and securing country demand. This approach could be expanded to include other vaccines, such as Cholera, Typhoid, or potentially in the future TB (tuberculosis).
- 3.3 The objectives of the approach in former Gavi-eligible countries would be to **continue access to appropriate pricing** and **sustain immunisation performance** with a focus on targeted technical support to reach **zero dose** children. In both never and former Gavi-eligible MICs the objective would

⁴ The interlinkages between Gavi policies will be fully elaborated in the detailed paper in 2020.

be to provide targeted support to stimulate the **sustainable introduction of key missing vaccines**. Crucially, it would have a focus on supporting MICs to both **mobilise and maximise their domestic resources** for immunisation. Moreover, enabling the introduction of these key vaccines will address both **inter-country and intra-country equity** concerns. In many of these countries, these vaccines are already available but only in the private market at a substantial out-of-pocket price. The approach would leverage the Alliance's comparative advantages, build on partners' widespread expertise, recognise and work to maximise the considerable existing capacity of MICs, all whilst drawing on lessons from previous initiatives and Gavi's post-transition experiences. Finally, the approach would seek a balance between country needs and being attractive to manufacturers, all at a reasonable cost to the Alliance.

- 3.4 The approach, which is developing iteratively in response to stakeholder feedback, concentrates on three inter-linked and mutually reinforcing components, which when executed together directly address the priority bottlenecks identified by stakeholders (Figure 1). The components of the model will be applied selectively to different groups of countries given their differing needs and crucially, the relevance and effectiveness of the different levers in mobilising and maximising the efficiency of domestic resources.

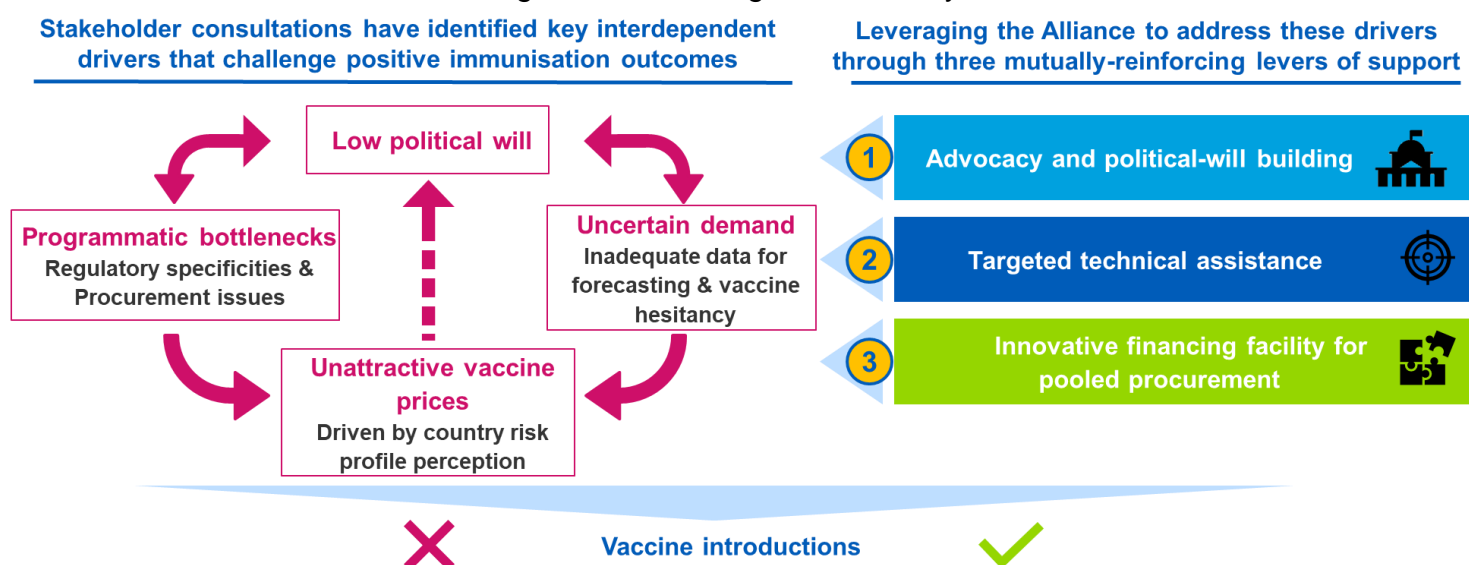


Figure 1: The interdependent drivers to immunisation challenges and proposed MICs approach to address them

Component 1: Advocacy and political-will building

- 3.5 The Alliance will use its convening power to strengthen countries' political commitment to immunisation, the focus on zero dose children, and NVIs. In former Gavi-eligible countries, there will be a specific emphasis on advocacy to maintain the gains made whilst under Gavi support to prevent backsliding. Efforts could include developing and sharing information on the value of vaccines (particularly showcasing the significant benefit to the poor) to create a persuasive investment case and bringing together key partners to engage with country leadership to influence decision-making towards

investing in sustainable immunisation programmes. Leveraging the voices of diverse partners towards a single objective, immunisation, is one of the most powerful tools of the Alliance.

Component 2: Targeted technical assistance

- 3.6 This component would leverage the expertise and country presence of Alliance partners and extended partners to provide country-specific technical assistance based on need and to build synergies between countries and efficiencies within countries. For the former Gavi-eligible countries, the proposed approach would institutionalise Gavi's existing post-transition engagement but with high focus on zero dose children. For all countries, the Alliance would bring real added value as a 'disruptor', building on our legacy of taking new technologies to scale e.g. actively shaping the market for new technologies and pioneering new ways of creating more efficient supply chains. Engaging with MICs in this way is a real opportunity to bring innovations for the optimisation of supply chains.
- 3.7 The approach would have a highly proactive attitude to collaboration. Examples of potential opportunities for collaboration include:
 - **Existing partners: WHO** would be a critical partner for a MICs approach that builds on their expertise and valuable efforts from the implementation of the MICs Strategy and under the direction of IA2030. WHO's regulatory expertise will be a vital part of the support offered to countries and WHO Regional Offices are a key platform for learning and information exchange. For example, Gavi could support WHO AFRO exploratory efforts to create a centre of excellence at the University of Cape Town for NITAGs.
 - **Opportunities to leverage wider partners:** The **Global Fund** has established relationships with MICs that can be a gateway to a broader engagement with Gavi. Some areas identified for cooperation include building political will and procurement and regulatory capacities. Also, conversations with the **Asian Development Bank** have been initiated to leverage their funding in Gavi's approach to supporting MICs.
 - **Building and strengthening existing country platforms:** Recognising the existing capacity in MICs, there is an opportunity to expand south-to-south exchanges among MICs and Gavi countries. Examples of opportunities identified are the Association of Southeast Asian Nations (ASEAN) and the Southern and Eastern European Health Network (SEEHN) efforts on regulatory streamlining and political will.
- 3.8 Following feedback from countries and early feedback from Board constituencies, the Secretariat is moving away from including broad-brush vaccine catalytic financing towards only providing such support in a very targeted way based on specific country needs. This may also be an area of support differentiation between former and never Gavi-eligible countries. This support could play a critical role in motivating new vaccine introductions and this is a key issue for further reflection and consultation.

Component 3: Innovative financing facility for pooled procurement

- 3.9 Gavi could augment UNICEF SD's existing procurement model by resourcing an innovative financing facility that UNICEF SD is currently constructing to support MICs. This facility would have two key roles: first, to provide long-term demand guarantees to suppliers and second to provide liquidity for country-bridge financing to ensure short-term predictability and payment of invoices to suppliers by leveraging Gavi's financing capacities. These two features would reduce a critical risk to manufacturers (unpredictable demand) and a key bottleneck to countries (pre-payment). This financing facility would thereby enable the procurement of key vaccines for MICs and may also support procurement of essential related commodities (e.g. cold chain equipment).
- 3.10 The financing facility would have the ability to guarantee commitments by countries to self-finance multi-year volumes of specific vaccine products over the duration of long-term agreements (LTAs)⁵. Manufacturers would deliver the supply as per the LTAs and offer countries more attractive vaccine prices⁶, in line with tiered pricing principles, justified by the risk-reduction features of the mechanism, larger purchase volumes, and LTAs.
- 3.11 In addition, the Secretariat is exploring ways to standardise manufacturer price commitments to ensure that future Gavi transitioning countries can sustain their immunisation programmes even after these price commitments expire. This could translate into time-limited price freezes offering Gavi-like prices to former Gavi-eligible countries.
- 3.12 The proposed MICs approach was presented to manufacturers with products currently in scope of Gavi MIC engagement. Overall the proposal was well received and while manufacturers recognised the attractiveness of the de-risking features of the financing facility, they expressed interest to further understand the details of the approach. Manufacturers emphasised the importance of addressing barriers to NVIs which are not related to pricing to ensure countries' commitment to introduction and demand over the long-term. This was particularly highlighted with regards to streamlining regulatory and procurement processes⁷. Although the respect of tiered pricing principles was welcomed by all manufacturers, representatives of the IFPMA constituency highlighted the risk of international price referencing and the need to consider modalities of price transparency that don't undermine their ability to offer attractive prices.

4. Next steps

- 4.1 Through a three-pronged approach, the Alliance could bring together elements of past efforts which were not sufficiently harmonised and

⁵ The payment for the vaccines would be solely coming from countries' own domestic resources

⁶ Compared to what would have been offered outside of the mechanism

⁷ Issues raised by manufacturers included supporting the adoption of 'Facilitated Regulatory Pathways', harmonising post-approval change requirements and timelines, country labelling requirements, and individual country release testing.

therefore didn't fully complement each other to achieve the desired outcomes. The Alliance will build on UNICEF SD's tendering experience for MICs and WHO's experience with the MICs strategy, and supplement with the right amount of innovative financing, convening power and voices of all partners to operationalise a holistic support package to sustain immunisation gains and overcome the barriers to NVIs in MICs.

- 4.2 The Secretariat will continue consulting with countries, Alliance partners, manufacturers and other key stakeholders to ensure a fully nuanced understanding of needs and potential responses, including a deep-dive with select never Gavi-eligible countries. Further work on designing the financing facility for procurement and parameters of the tiered pricing will also be undertaken. The Secretariat aims to present a detailed proposal of the scope and approach to the PPC in May 2020.

Section C: Actions requested of the Board

This report is for information only.

Annexes

Annex A: Diagram of MICs Approach and the country journey