

Beyond the "Gavi-Eligible"

High-Leverage Opportunities for Gavi to Enhance Vaccine Access and Uptake in Ineligible Middle-Income Countries

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Abstract

The global locus of undervaccination is increasingly shifting from the poorest countries in the world—which are eligible for support from Gavi, the Vaccine Alliance (Gavi)—to middle-income countries (MICs) that do not qualify for traditional Gavi support. Given these growing challenges, Gavi must rethink its engagement with those MICs that are ineligible for traditional support. Although this engagement is intended to be "catalytic" and has been intentionally targeted to country needs, it also has been relatively smallscale and ad hoc. Gavi's next five-year strategic period from 2026 to 2030, known as "Gavi 6.0," offers a window of opportunity for its board and leadership to consider new and different ways for Gavi to engage with MICs to advance global vaccine access and improve vaccination outcomes. To have the greatest impact in this context, Gavi must lean into its comparative advantage in market shaping and demand consolidation to drive its contributions to global vaccination efforts with finite resources. We offer recommendations for Gavi to operationalize broader engagement with MICs, specifically by enabling an expanded cohort of MICs to access more affordable prices for both newer, costlier vaccines and future vaccines via opt-in framework agreements and by supporting a global coordinating hub to shape a forward-looking immunization innovation agenda.

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Introduction

Although vaccines are typically administered in a private interaction between a health worker and a patient, "vaccination" writ large is a global issue. All countries, at all income levels, have an interest in ensuring that existing vaccines are accessible to their populations, including via locally affordable pricing and supply security; promoting vaccine uptake among eligible populations to maximize both individual protection and population-level protection via "herd immunity"; and, to some extent, developing safe and effective new vaccines to address existing and potential health threats.¹

Gavi, the Vaccine Alliance (Gavi), is a major global initiative that seeks to promote global vaccination and serve this global public good. Gavi was founded in 2001 with the mission "to save lives and protect people's health by increasing equitable and sustainable use of vaccines." In the nearly 25 years since its founding, Gavi has targeted its support to the poorest countries, with gross national income (GNI) per capita under a preset threshold; this GNI threshold has ranged from \$1,000 in 2001 to \$1,810 as of 2024.

In Gavi's early years, this focus was clearly logical; the 77 eligible countries that met Gavi's eligibility threshold were previously "ground zero" for global undervaccination. As of 2005, for example, 84 percent of the world's zero-dose children—those who have not received any routine vaccination—lived in Gavi-eligible countries.³ However, the situation is changing at a rapid pace. Increasingly, the global locus of undervaccination is moving from Gavi-eligible countries—the poorest in the world—to somewhat wealthier middle-income countries (MICs) that no longer qualify for traditional Gavi support.

There are several trends underlying this broad phenomenon, which will be discussed and substantiated at greater length in Section 1. First, since its founding in 2001, Gavi has seen substantial success in supporting partner countries to raise vaccination rates. Vaccination coverage gaps between the poorest countries and wealthier MICs have narrowed and, in some cases, even closed. Second, many large MICs have already transitioned from Gavi support, or are expected to do so by 2030, because their GNIs per capita currently or will soon exceed the Gavi eligibility threshold. Because Gavi's eligibility model is based on income and not on programmatic readiness or coverage rates, countries may transition without having first achieved high coverage rates for certain vaccines. Third, MICs that have never been eligible for Gavi support sometimes face higher vaccine prices than those that are made available to Gavi-eligible peers, especially for newer vaccines and when self-procuring. These countries have seen slow introduction of new World Health Organization (WHO)-recommend vaccines, in large part owing to affordability and cost-effectiveness challenges.

¹ Many low- and middle-income countries would strongly prioritize affordable and reliable access to existing vaccines over development of new vaccines; however, these same countries might nonetheless benefit from development of new vaccines if and when they come to market and are offered at locally affordable prices.

 $^{2 \}quad \text{``About Our Alliance,'' Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/our-alliance/about.} \\$

^{3 &}quot;GAVI Alliance Progress Report 2005," Gavi, The Vaccine Alliance, 2005, https://www.gavi.org/sites/default/files/publications/progress-reports/Gavi-Progress-Report-2005.pdf.

(There are 57 countries classified as MICs that have never been eligible for Gavi support, including 13 lower-middle-income countries and 44 upper-middle-income countries.)⁴

Gavi-ineligible MICs now account for a large and growing share of the global undervaccination challenges. Yet all MICs—both those that have transitioned from Gavi support and those that were never Gavi-eligible—are facing this challenge without coordinated, comprehensive support from the international community. Despite the tremendous international importance of vaccination, no single international organization has the global mandate, broadly speaking, to support countries to procure vaccines, ensure high coverage, and reach global vaccination goals. There are, of course, several organizations with partial mandates around vaccine development, access, affordability, quality, coverage, and innovation, including the WHO, the Coalition for Epidemic Preparedness Innovations (CEPI), the United Nations Children's Fund (UNICEF), regional procurement platforms and technical blocs (e.g., the Pan American Health Organization [PAHO]), philanthropies, and even Gavi itself. These organizations engage with some noneligible MICs through narrowly targeted forms of support (see Section 2). However, for most countries, the overall support provided by these mechanisms is fragmented, inconsistent, and incomplete. Most MICs receive limited support or services in addressing key vaccination obstacles.

If Gavi wishes to remain the premier organization supporting global vaccine access, it must expand its business model beyond the group of countries eligible for traditional support, toward facilitating and supporting better vaccination outcomes in MICs. Yet Gavi is an initiative with limited financial and technical resources, at least relative to the scale of the challenges confronting the entire cohort of MICs. MICs, as a collective, have larger populations, higher health spending, and greater overall resources compared to the cohort of lower-income countries that are eligible for traditional forms of Gavi support. To have the greatest impact in this context, Gavi must lean into its comparative advantage and be strategic about where it can use its finite resources to make the largest possible contributions to global immunization goals. Gavi's next five-year strategic period from 2026 to 2030, known as "Gavi 6.0," offers a window of opportunity for its board and leadership to consider new and different ways for Gavi to engage with MICs, as well as help Gavi prepare for further evolution in the post–Sustainable Development Goals era.

This paper will first demonstrate why MICs are now central to global challenges of undervaccination. It will describe the specific challenges MICs face with vaccination and consider how these challenges differ across subcategories of MICs—for instance, formerly eligible Gavi countries compared with never Gavi-eligible countries. Second, it will review Gavi's existing efforts and modes of support in MICs, highlight what we know about how these efforts have worked to date, and assess where they continue to fall short. Finally, it will offer three ideas for how Gavi can expand its engagement with MICs, building on its comparative advantage in market shaping, for maximum global benefits.

⁴ Authors' calculations based on fiscal year (FY) 2024 World Bank income groups and 2024 Gavi eligibility: "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups; "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility.

Section 1: Why ineligible middle-income countries are becoming "ground zero" for global under-immunization

Key Point 1: Non-Gavi MICs now account for a large—and increasing—share of the world's undervaccinated population, with a growing concentration of zero-dose children

At Gavi's founding, the poorest countries in the world—those that were eligible for Gavi support—had very low uptake of basic childhood vaccinations. In 2000, Gavi-eligible countries had about 65 percent coverage of the third dose of the combined diphtheria, tetanus, and pertussis containing vaccine (DTP3); around 20 percent coverage of the Hepatitis B vaccine; and 0 percent coverage of the Haemophilus influenzae type b (Hib) vaccine. Since then, Gavi's investments have helped eligible governments achieve remarkable gains in vaccine coverage. As of 2022, countries that remained Gavi-eligible had pentavalent coverage of 81 percent (including DTP3, Hepatitis B, and Hib protection)—just slightly lower than global coverage rates (84 percent). Perhaps most remarkably, Gavi reported in 2022 that the "breadth of protection" across all vaccine types was now higher in Gavi-eligible countries than in the rest of the world.

Yet the global picture is not quite so rosy. A staggeringly high number of children around the world continue to miss out entirely or partially on routine vaccination, leaving them unprotected against preventable illnesses. In part, but not entirely, due to Gavi's own success in raising coverage rates within eligible countries, a growing proportion of these children now live within the cohort of *non-Gavi* MICs—including both formerly eligible countries *and* never-eligible countries (see Table A1 in Appendix A). Country experiences vary among the diverse cohort of non-Gavi MICs, but there are several alarming data points.⁸

First, several larger MICs that have transitioned from Gavi still contain significant pockets of underimmunized groups, often concentrated in specific geographic regions or socioeconomic subgroups (see summary breakdown in Table 1). In the examples of Angola and Bolivia—both lower-middle-income countries that transitioned from Gavi support in 2017—DTP3 coverage is 42 percent and 69 percent, respectively, and coverage of the second dose of the measles containing vaccine (MCV2) is 25 percent and 49 percent, respectively, as of 2022 (see Table A1 in Appendix A

⁵ *GAVI Alliance Progress Report 2008*, Gavi, The Vaccine Alliance, 2008, https://www.gavi.org/sites/default/files/publications/progress-reports/Gavi-Progress-Report-2008.pdf.

^{6 &}quot;Immunization Coverage," World Health Organization (WHO), last accessed March 22, 2024, https://www.who.int/news-room/fact-sheets/detail/immunization-coverage.

⁷ Breadth of protection is defined as the average vaccination coverage across key Gavi-supported vaccines. See: "Eight Things You Need to Know about the State of Global Immunization," Gavi, the Vaccine Alliance, July 18, 2023, https://www.gavi.org/vaccineswork/eight-things-you-need-know-about-state-global-immunisation; Annual Progress Report 2022, Gavi, the Vaccine Alliance, last updated January 2024, https://www.gavi.org/progress-report.

⁸ Robert John Kolesar, Rok Spruk, and Tsheten Tsheten, "Evaluating Country Performance After Transitioning From Gavi Assistance: An Applied Synthetic Control Analysis," *Global Health: Science and Practice* 11, no. 4 (2023), https://doi.org/10.9745/GHSP-D-22-00536.

for breakdown by country). Other countries, like Honduras and Bolivia, have seen coverage rates of certain vaccines drop off following transition from Gavi support.⁹

TABLE 1. Summary breakdown of 108 MICs (classifications for FY 2024), addta for most recent year

Status of Gavi Eligibility	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)°	Current Health Expenditure (USD Millions) ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Total Births (Thousands) ^c	Share of Total MIC Birth Cohort (%)°
Transitioning by 2030	2,454	3.25	3,959	79	58	14,718	15
Not transitioning by 2030	1,543	2.75	1,632	80	67	15,236	16
Former Gavi (no India)	5,159	2.46	50,800	87	82	20,907	22
Indiad	2,411	4.16	104,211	93	90	23,114	24
Never Gavi	7,423	1.33	14,063	86	78	23,563	24

Notes: (a) See Table A1 in Appendix A for breakdown by country. Number and share of zero-dose children are excluded from this summary table because the data include imprecise estimates for some countries. (b) Figures reflect averages across the group. (c) Figures reflect the sum of values for the group. (d) India is separated out to avoid skewing summary statistics, given India's large economy and birth cohort. GDP = gross domestic product; USD = U.S. dollars.

Sources: See Table A1 in Appendix A for all sources.

Second, coverage for routine vaccines also remains low in some never Gavi-eligible MICs, including the Philippines (DTP3 = 72 percent; MCV2 = 64 percent) and Equatorial Guinea (DTP3 = 53 percent and MCV2 = 13 percent). In addition, immunization coverage remains highly inequitable in some non-Gavi MICs, most notably those with large birth cohorts. For example, coverage of age-appropriate vaccinations among children aged 12 to 23 months in the Philippines varies across regions from 15 percent to 82 percent. (The Philippines has never been eligible for traditional Gavi support but is currently eligible for limited support under the MICs Approach, discussed at greater length in Section 2.)

Third, an increasing concentration of zero-dose children (those who have not received their first dose of the DTP vaccine) live in non-Gavi MICs (see Table A1 in Appendix A for additional data).¹²
Nearly a quarter of zero-dose children live in just five MICs that are ineligible based on

⁹ Brian Webster, Lydia Regan, and Victoria Fan, "After Graduation, How Do Gavi-Eligible Countries Fare?," Center for Global Development (blog), March 20, 2024, https://www.cgdev.org/blog/after-graduation-how-do-gavi-eligible-countries-fare.

^{10 &}quot;Input to the WHO/UNICEF Estimates of National Immunization Coverage (WEUNIC)," WHO, July 17, 2023, https://www.who.int/publications/m/item/wuenic_input.

¹¹ See Map 10.1 in *Philippines DHS*, 2022—Final Report, DHS Program, June 2023, https://dhsprogram.com/publications/publication-FR381-DHS-Final-Reports.cfm.

^{12 &}quot;Zero-Dose: The Children Missing Out on Life-Saving Vaccines," UNICEF, April 2023, https://data.unicef.org/resources/zero-dose-the-children-missing-out-on-life-saving-vaccines/.

Gavi's standard eligibility criteria: India (7.92 percent of global zero-dose children), Angola (4.32 percent), Indonesia (4.02 percent), the Philippines (4.48 percent), and Brazil (3.03 percent).

This general trend—an increasing concentration of undervaccination in Gavi-ineligible MICs—is likely to accelerate in the coming years as additional countries transition from Gavi support. Most notably, Nigeria is currently projected to transition from Gavi support in 2028, even though its DTP3 coverage rates average just 62 percent nationwide and 51 percent in the 20 least-vaccinated districts. And, as of 2022, Nigeria is home to 2.2 million zero dose children, nearly 16 percent of the world's unvaccinated population (see Table A1 in Appendix A). At the national level, this means that Nigeria is likely to transition from Gavi support long before reaching herd immunity, even for routine vaccines. Cambodia, Comoros, the Kyrgyz Republic, Nepal, Senegal, and Tajikistan could also cross Gavi's eligibility threshold by 2040, losing access to full support from Gavi. 15

Key Point 2: Many MICs are getting less for more with their immunization expenditures

Although the underlying factors driving differences may vary, non-Gavi MIC governments have, on average, significantly higher expenditures on routine immunization. For example, in 2022, the average Gavi-ineligible MIC spent \$170.13 on routine immunization per surviving infant—about *six times* as much as Gavi-eligible MICs (\$26.93) and low-income countries (LICs) (\$29.04). Moreover, despite significantly higher immunization expenditures by MIC governments, children in Gavi-ineligible MICs receive *fewer* vaccines on average than do their peers in Gavi-eligible countries. Many MICs have not yet introduced newer WHO-recommended vaccines, such as the pneumococcal conjugate vaccine (PCV), the human papillomavirus (HPV)

¹³ Share of zero-dose children from "WUENIC Analytics," UNICEF, last accessed March 22, 2024, https://unicef-dapm. shinyapps.io/wuenic-analytics-2023/. India transitioned from Gavi support in 2021 and now has a special partnership with Gavi until 2026 with a \$250 million envelope and particular focus on reaching zero-dose children. See "Gavi and Government of India Establish New Partnership to Protect Millions of Children by 2026," Gavi, the Vaccine Alliance, February 3, 2023, https://www.gavi.org/news/media-room/gavi-and-government-india-establish-new-partnership-protect-millions-children-2026. Angola, the Philippines, and Indonesia are eligible under the MICs Approach, but this is for small-scale and one-off targeted forms of support (see Section 2). See also: "List of Countries and Economies Eligible for Support under the MICs Approach as of 1 July 2023," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/sites/default/files/programmes-impact/support/Countries-and-economies-eligible-for-support-under-Gavi-MICs-Approach.pdf.

^{14 &}quot;Nigeria," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/programmes-impact/country-hub/africa/nigeria.

¹⁵ Morgan Pincombe et al., "Projections of Eligibility and Transition Trajectories up to 2040: Implications for Gavi's Next Strategic Period and Beyond," Center for Global Development, December 14, 2023, https://www.cgdev.org/publication/projections-eligibility-and-transition-trajectories-2040-implications-gavis-next.

¹⁶ Authors' calculations based on total expenditure of vaccines from 2022 and number of births surviving to age 1 from 2021. See: "Financing for Immunization Country Dashboard," WHO, last accessed March 22, 2024, https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/planning-and-financing/immunization-financing-indicators; "World Population Prospects 2022," United Nations Department of Economic and Social Affairs, Population Division, 2022, https://population.un.org/wpp/Download/Standard/MostUsed/.

vaccine, and the rotavirus vaccine (RV).¹⁷ Gavi-eligible countries have access to support for new vaccine introductions, but once they transition to fully self-financing, this support is significantly downsized and more time-limited (see Section 2).

The slow introduction of newer vaccines is especially apparent in MICs that have recently transitioned from Gavi support, as well as in never Gavi-eligible countries that are just above Gavi's eligibility threshold (see Figure 1). For example, 93 percent (26/28 total) of Gavi-eligible MICs have introduced PCV, but only 78 percent (18/23 total) of former-Gavi MICs and 74 percent (42/57 total) of never Gavi-eligible MICs have incorporated PCV into national immunization programs. Importantly, vaccine adoption decisions require delicate trade-offs between cost and health benefit, and countries may be rationally health-maximizing if the opportunity cost of a new vaccine investment outweighs its expected health impact. Nevertheless, limited uptake of lifesaving vaccines by these countries—however rational—is a missed opportunity for new vaccine technologies to translate into public health impact.

100% 93% 90% 81% 79% 78% 77% 80% 74% 70% 70% 60% 54% 54% 52% 52% 50% 42% 40% 30% 20% 10% 0% **PCV** Introductions **HPV Vaccine Introductions RV** Introductions ■ Low income (n=26) ■ Gavi-eligible MIC (n=28) ■ Former-Gavi MIC (n=23) ■ Never-Gavi MIC (n=57)

FIGURE 1. Introductions of new or underutilized vaccines by country income group and Gavi eligibility status

 ${\it Note:} \ {\tt Data} \ reflect introductions into national immunization programs as of February 20, 2024, using FY 2024 World Bank income groups and 2024 Gavi eligibility.$

Sources: International Vaccine Access Center, "VIEW-hub," Johns Hopkins Bloomberg School of Public Health, last accessed February 20, 2024, https://view-hub.org/; "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups; "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility.

¹⁷ This pattern is particularly visible with PCV and RV introductions. However, a higher share of Gavi-ineligible countries has introduced the HPV vaccine compared to Gavi-eligible countries, as shown in Figure 1.

¹⁸ International Vaccine Access Center, "VIEW-hub," Johns Hopkins Bloomberg School of Public Health, last accessed February 20, 2024, https://view-hub.org/.

¹⁹ Jason Zhu et al., "Opportunities to Accelerate Immunization Progress in Middle-Income Countries," *Vaccine* (2023), https://doi.org/10.1016/j.vaccine.2023.06.079.

A key factor driving slow adoption of new vaccination is pricing. Non-Gavi MICs face considerably higher and more variable vaccine prices than Gavi-eligible peers, especially for newer vaccines such as PCV, HPV vaccine, and RV, as well as when self-procuring. For example, Gavi-eligible MICs access a negotiated price of \$4.42 per dose for HPV vaccine, but non-Gavi lower-middle-income countries and upper-middle-income countries pay an average of \$12.70 and \$48.40, respectively, if self-procuring, or between \$8.27 and \$13.47 to procure doses through PAHO or the UNICEF Supply Division (SD) (see Table 2). Average prices are roughly two to three times higher for non-Gavi MICs. Applied to the self-procuring of the self-proc

At these higher prices, some vaccinations may fail local cost-ineffectiveness thresholds, meaning that they are functionally unaffordable for MIC governments. ²² For example, a 2019 cost-effectiveness analysis in Thailand (which has never been eligible for Gavi support) found that the 10-valent PCV was not locally cost-effective when herd effect is not considered. ²³ Similarly, a 2022 analysis found that the GARDASIL-9 HPV vaccine would not be cost-effective in the Philippines (which was never eligible for standard Gavi support, but is now eligible for Gavi's MICs Approach). ²⁴ The same 2022 analysis also found that the Ceravix, Cecolin, and GARDASIL-4 HPV vaccines would be cost-effective in the Philippines, underscoring the importance of uptake of lower cost products.

²⁰ A range of factors affect the price of vaccinations, but purchasing through pooled procurement mechanisms, such as the UNICEF Supply Division, can help maintain larger demand pools and therefore enable prices that on average are comparatively lower, including through specific time-limited arrangements offered by UNICEF. However, not all countries choose to or are able to purchase through these mechanisms (see Section 2).

²¹ A comparison with an earlier analysis looking at price levels in 2016 suggests that the gaps between prices available to Gavi-eligible and non-eligible MICs may have narrowed slightly, though the precise reason behind this trend is unknown. See Table 2 in Rachel Silverman et al., "Tackling the Triple Transition in Global Health Procurement," Center for Global Development, June 17, 2019, https://www.cgdev.org/better-health-procurement. See Table 1 in Janeen Madan Keller and Amanda Glassman, "Gavi's Role in Market Shaping and Procurement," Center for Global Development, June 24, 2019, https://www.cgdev.org/publication/gavis-role-market-shaping-and-procurement-progress-challenges-and-recommendations.

²² Even at lower market prices, certain vaccines may still not be locally affordable within some countries' highly constrained government budgets.

²³ Piyameth Dilokthornsakul et al., "An Updated Cost-Effectiveness Analysis of Pneumococcal Conjugate Vaccine among Children in Thailand," *Vaccine* 37, no. 32 (2019), https://doi.org/10.1016/j.vaccine.2019.06.015.

²⁴ This analysis was based on a two-dose regimen. See Cecilia L. Llave et al., "The Cost-Effectiveness of Human Papillomavirus Vaccination in the Philippines," Vaccine 40 (2022), https://doi.org/10.1016/j.vaccine.2022.05.025.

In 2022, the WHO updated its recommendations for the HPV vaccine, stating that a single-dose regimen can provide a comparable efficacy and durability of protection to a two-dose regimen, which may have implications for cost-effectiveness. See "WHO Updates Recommendations on HPV Vaccination Schedule," WHO, December 20, 2022, https://www.who.int/news/item/20-12-2022-WHO-updates-recommendations-on-HPV-vaccination-schedule. For broader discussion of the cost-effectiveness of HPV vaccination see Katie Regan, "Is HPV Vaccination Cost Effective," PATH, March 14, 2024, https://www.path.org/our-impact/articles/is-hpv-vaccination-cost-effective/.

Some MICs nevertheless have opted to adopt newer vaccines and must devote a large portion of their vaccine budgets to their purchase. PCV, HPV vaccine, and RV comprise approximately 34 percent, 22 percent, and 14 percent, respectively, of non-Gavi MICs' vaccine budgets on average. ²⁵ Ultimately, higher vaccine purchasing costs limit the overall reach of MICs' immunization expenditures.

TABLE 2. Price comparisons from vaccine purchases in 2020–2022 across country groups and by procurement mechanism

PCV

	Procurement Mechanism (n)	Average Price Per Dose (USD)	Range of Prices Per Dose (USD)	Total Annual Number of Doses (Millions)
	PAHO RF (1)	3.30	3.30-3.30	0.40
Gavi MICs	Self-procurement (1)	3.03	2.90-3.16	0.77
Gavi Mics	UNICEF SD (39)	3.22	2.00-14.50	213.30
	All (41)	3.21	2.00-14.50	214.47
	PAHO RF (4)	14.11	12.76-14.50	3.57
Non-Gavi LMICs	Self-procurement (3)	10.70	1.95–17.49	96.38
Non-Gavi LMICS	UNICEF SD (13)	6.99	2.00-25.00	10.84
	All (20)	8.97	1.95-25.00	110.79
	PAHO RF (11)	14.17	12.85-14.50	8.53
Non-Gavi UMICs	Self-procurement (14)	26.99	3.21-66.20	37.50
Non-Gavi UMICS	UNICEF SD (14)	11.68	2.90-43.60	3.51
	All (39)	18.58	2.90-66.20	49.54

HPV Vaccine

	Procurement Mechanism (n)	Average Price Per Dose (USD)	Range of Prices Per Dose (USD)	Total Annual Number of Doses (Millions)
	PAHO RF (1)	4.50	4.50-4.50	0.24
Gavi MICs	Self-procurement (1)	2.66	0.81-4.50	0.48
Gavi Mics	UNICEF SD (21)	4.51	1.43-6.49	20.66
	AII (23)	4.42	0.81-6.49	21.38
	PAHO RF (5)	8.27	4.50-10.51	1.20
Non-Gavi LMICs	Self-procurement (1)	12.70	11.60-13.81	1.48
Non-Gavi LMICs	UNICEF SD (8)	9.29	4.21-28.28	2.22
	All (14)	9.33	4.21-28.28	4.91
	PAHO RF (17)	10.49	9.58-19.96	3.09
Non Coulling	Self-procurement (7)	48.40	1.25-128.11	4.41
Non-Gavi UMICs	UNICEF SD (10)	13.47	4.50-28.28	1.59
	All (34)	18.87	1.25-128.11	9.10

²⁵ Tania Cernuschi et al., "Price Transparency Is a Step Towards Sustainable Access in Middle Income Countries," *BMJ* 368, no. 5375 (2020), https://doi.org/10.1136/bmj.l5375.

	Procurement Mechanism (n)	Average Price Per Dose (USD)	Range of Prices Per Dose (USD)	Total Annual Number of Doses (Millions)
	PAHO RF (3)	2.48	2.18-2.72	1.58
Gavi MICs	Self-procurement (2)	1.35	0.81-2.30	104.55
Gavi Mics	UNICEF SD (29)	1.72	0.60-6.50	118.73
	All (34)	1.73	0.60-6.50	224.87
	PAHO RF (5)	5.67	0.15-6.80	3.62
Non-Gavi LMICs	Self-procurement (1)	0.86	0.86-0.86	99.00
Non-Gavi LMICS	UNICEF SD (9)	3.66	0.70-9.00	8.88
	All (15)	4.05	0.15-9.00	111.51
	PAHO RF (10)	9.63	6.50-62.40	8.05
Non-Gavi UMICs	Self-procurement (7)	11.96	3.18-30.58	10.65
Non-Gavi UMICS	UNICEF SD (11)	5.46	0.70-9.50	1.94
	All (28)	8.64	0.70-62.40	20.64

Note: LMIC = lower-middle-income country. UMIC = upper-middle-income country.

Source: "Market Information for Access to Vaccines," World Health Organization, last accessed February 2024, https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a.

Key Point 3: MICs are still recovering from COVID-induced health and economic shocks and facing a period of fiscal tightening

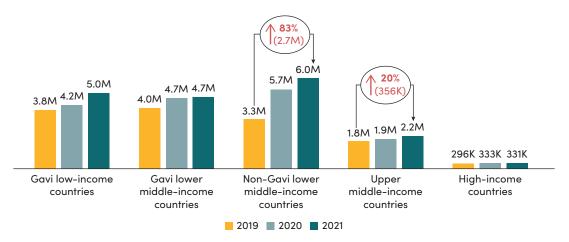
The COVID-19 pandemic disrupted routine immunization around the world. MICs were particularly hard-hit, experiencing significant declines in routine vaccination coverage. Many MICs were struggling with vaccine coverage long before the pandemic, but COVID-19 exacerbated these challenges, leading to stagnation and even backsliding in routine immunization coverage.

The majority of the top 10 countries that saw the greatest increase in children not receiving a first dose of DTP between 2019 and 2020 are not eligible for Gavi support. ²⁶ Perhaps most notably, non-Gavi lower-middle-income countries experienced an 83 percent increase in the number of zero-dose children between 2019 and 2021—an absolute increase of 2.7 million zero dose children (Figure 2). ²⁷

²⁶ Of the top 10 countries, only Pakistan (lower-middle-income country), Mozambique (LIC), the United Republic of Tanzania (lower-middle-income country), and Mali (LIC) are eligible for Gavi support. See "COVID-19 Pandemic Leads to Major Backsliding on Childhood Vaccinations, New WHO, UNICEF Data Shows," UNICEF, July 15, 2021, https://www.unicef.org/press-releases/covid-19-pandemic-leads-major-backsliding-childhood-vaccinations-new-who-unicef-data. FY 2024 World Bank income groups are from "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups; and 2024 Gavi eligibility is from "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility.

²⁷ The significant increase in the number of zero-dose children in India during the pandemic drove the overall increase for lower middle-income countries. See WUENIC 2019–2022 data summarized in Figure 1 in Pawan Kumar et al., "Balancing Routine and Pandemic: The Synergy of India's Universal Immunization Program and COVID-19 Vaccination Program," Vaccines 11, no. 1776 (2023), https://doi.org/10.3390/vaccines11121776.

FIGURE 2. Number of zero-dose children by country income group and Gavi eligibility, 2019–2021



Source: "Performance of Middle-Income Countries: Impact Goals, Baseline-2021 Immunization Agenda 2030," Immunization Agenda 2030, July 2023, 6, https://www.immunizationagenda2030.org/images/documents/IA2030_Performance_of_MIC_Draft_Summary_for_Comment_July_2023_.pdf.

Although immunization programs in MICs are recovering from pandemic-era disruptions, including with the support of Gavi and other partners, coverage rates have not yet returned to prepandemic levels. For example, coverage of DTP3 in Gavi-eligible countries in 2022 remained 2 percentage points lower than in 2019, and estimates suggest that there are about 1 million more zero-dose children in 2022 than in 2019.²⁸

Even while routine immunization coverage is rebounding, many MICs are witnessing fiscal tightening, with consequences for spending in social sectors, including for essential health services like immunization. Although almost all countries around the world increased overall levels of health spending during the COVID-19 pandemic, this trend is quickly reversing. ²⁹ Today, high inflation, rising interest rates, and currency depreciation are the new fiscal realities. ³⁰ Projections of future expenditure trajectories also suggest impending challenges, particularly for the cohort of MICs.

²⁸ Annual Progress Report 2022, Gavi, the Vaccine Alliance, last updated January 2024, https://www.gavi.org/progress-report.

²⁹ Amanda Glassman, Janeen Madan Keller, and Eleni Smitham, "The Future of Global Health Spending Amidst Multiple Crises," Center for Global Development, January 17, 2023, https://www.cgdev.org/publication/future-global-health-spending-amidst-multiple-crises.

^{30 &}quot;Sharp, Long-lasting Slowdown to Hit Developing Countries Hard," World Bank, January 10, 2023, https://www.worldbank.org/en/news/press-release/2023/01/10/global-economic-prospects; Confronting Inflation and Low Growth: OECD Economic Outlook, Interim Report September 2023, Organization for Economic Cooperation and Development, September 2023, https://www.oecd.org/economic-outlook/september-2023/.

Notably, government expenditure for health is projected to stagnate in 34 percent (27/80) and contract in 25 percent (20/80) of non-Gavi MICs, respectively. 31

Further, many MICs are facing mounting levels of debt with debt servicing accounting for unsustainable levels of overall government revenues, which could constrain fiscal space for immunization, among other consequences. ³² For example, Lao PDR and Ghana are currently in debt distress and Kenya is at high risk, according to the World Bank's Debt Sustainability Analysis. ³³ These countries are in Gavi's accelerated transition phase and are already at risk of falling below the GNI threshold and becoming reeligible for Gavi support before 2040, according to recent projections based on economic growth estimates. ³⁴ Additional tailored interventions are needed to support MICs in addressing these deteriorating fiscal conditions to protect and expand immunization coverage.

Section 2: Gavi's existing approach to supporting middle-income countries

Recognizing the challenges facing MICs, Gavi has extended some forms of financing support and technical assistance to countries that are not eligible for traditional forms of support.³⁵ Although Gavi's approach to date has been intentionally catalytic and targeted to country-specific needs, it has been relatively small-scale, temporary, and ad-hoc. This section provides an overview of Gavi's engagement with different MIC subgroups and spotlights specific challenges and gaps associated with approaches to date.

³¹ Author's calculations based on Christoph Kurowski et al., From Double Shock to Double Recovery, Technical Update 2: Old Scars, New Wounds, World Bank, September 2022, https://openknowledge.worldbank.org/server/api/core/bitstreams/76d5786b-9501-5235-922acaa71f99f0fc/content. FY2024 World Bank income groups are from "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups; 2024 Gavi eligibility is from "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility.

³² Victoria Fan and Sanjeev Gupta, "What's Rising Debt Got to Do With Health Spending?," Center for Global Development (blog), January 13, 2023, https://www.cgdev.org/blog/whats-rising-debt-got-do-health-spending.

^{33 &}quot;Debt Sustainability Analysis," World Bank, last accessed December 4, 2023, https://www.worldbank.org/en/programs/debt-toolkit/dsa.

³⁴ Morgan Pincombe et al., "Projections of Eligibility and Transition Trajectories up to 2040: Implications for Gavi's Next Strategic Period and Beyond," Center for Global Development, December 14, 2023, https://www.cgdev.org/publication/projections-eligibility-and-transition-trajectories-2040-implications-gavis-next.

³⁵ Beyond support from Gavi, MICs have access to various streams of technical support and funding from regional and global initiatives and platforms. Still, overall support is fragmented, and arguably insufficient to address the current scale of immunization challenges in these contexts. Examples include the ProVac Initiative in the Americas; the African Vaccine Regulatory Forum in Africa; the Association of Southeast Asian Nations Vaccine Security and Self-Reliance Working Group; UNICEF's Vaccine Independence Initiative; WHO's Market Information for Access to Vaccines; and the Learning Network for Countries in Transition. See "Middle-Income Countries," Immunization Agenda 2030, last accessed March 22, 2024, 7, https://www.immunizationagenda2030.org/images/documents/IA2030_MIC_Annex_draft_FINAL.pdf.

Overview of Gavi support available to different categories of MICs

The below section details the scope and eligibility criteria for various modalities of support available to different subgroups of MICs. For comparison purposes, we first provide a high-level overview of the modalities of support available to MICs that are currently eligible for traditional Gavi support, then dive deeper into the types of support available for MICs that have transitioned from Gavi support (former Gavi-eligible) or have never been eligible for Gavi support (never Gavi-eligible), including those that are classified as fragile and conflict-affected.

• Gavi eligible MICS with GNI per capita <\$1,810

The 28 eligible lower-middle-income countries that are eligible for Gavi support are categorized under either the preparatory transition or the accelerated transition phase based on specific GNI per capita cut-offs. ³⁶ The level of copayment required increases as countries move through Gavi's transition phases, but the types of Gavi support that are broadly available to eligible MICs remain the same.

In terms of vaccine support, MICs can receive financing for Gavi-supported vaccines that are centrally procured (via UNICEF SD or PAHO Revolving Fund), alongside country obligations for cofinancing. In addition, Gavi offers a range of funding streams to support systems strengthening, including Health Systems Strengthening and Cold Chain Equipment Optimization Platform, along with vaccine implementation support, such as Vaccine Introduction Grants and Operational Cost grants. ³⁷ Finally, countries have access to other technical assistance and financial support through a partnership engagement framework and targeted country assistance delivered through Gavi's Alliance partnerships.

Former Gavi-eligible and never Gavi-eligible MICs with GNI per capita <\$4,465
 and/or IDA-eligible

Gavi's support for MICs that are not eligible for traditional Gavi financing is primarily governed by its "MICs Approach," alongside other forms of adapted support intended for specific subgroups of countries, including those classified as fragile and conflict-affected. Nineteen countries that have

³⁶ See more here: "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility.

^{37 &}quot;Annex A: Framework for Gavi Funding to Countries," Gavi, the Vaccine Alliance, December 8, 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/7-8-dec/11a%20-%20Annex%20A%20-%20Framework%20 for%20Gavi%20Funding%20to%20Countries.pdf; "Gavi Application Process Guidelines," Gavi, the Vaccine Alliance, April 2023, https://www.gavi.org/sites/default/files/support/ApplicationProcess_Guidelines.pdf.

transitioned from Gavi to date as well as 27 never Gavi-eligible countries are eligible under the MICs Approach. 38

The MICs Approach was approved by the Gavi board in two stages owing to COVID-19—first in December 2020 and subsequently in June 2022—and is intended to cover the 5.0 strategic period from 2021 to 2025. Gavi's MICs Approach provides \$300 million in targeted funding—a meaningful but relatively modest amount. Until To further put this total into context, this envelope accounts for about percent of Gavi's forecasted expenditure for the 5.0 strategic period and less than 0.02 percent of total health expenditure for MICs.

The overall objective of Gavi's MICs Approach is twofold: first, preventing backsliding in vaccine coverage in *former Gavi-eligible* countries; and second, supporting introduction of key missing vaccines (e.g., PCV, HPV vaccine, RV) in both *former Gavi-eligible and select never Gavi-eligible countries* (specifically never-eligible lower-middle-income countries with GNI per capita <\$4,465 and additional IDA-eligible countries).⁴²

Under the first objective, support to prevent backsliding in former Gavi-eligible countries includes targeted investments to address specific immunization barriers and reach zero-dose children. Four former Gavi-eligible countries have been prioritized for support as per publicly available documentation: Angola, Bolivia, Honduras, and Indonesia. Under the second objective, Gavi provides a combination of technical assistance and flexible funding support, including funding to cover one-off costs associated with introductions or catalytic financing to introduce key missing vaccines (aimed to cover 50 percent of the first birth or target cohort).

³⁸ Guyana is eligible under Gavi's MICs Approach as a former Gavi-eligible country, as of July 2023. Guyana is categorized as a HIC based on the World Bank's FY 2024 income groupings. Venezuela is eligible under Gavi's MICs Approach as a never Gavi-eligible country, as of July 2023. Venezuela is not categorized in the World Bank's FY 2024 income groupings. See "List of Countries and Economies Eligible for Support under the MICs Approach as of 1 July 2023," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/sites/default/files/programmes-impact/support/Countries-and-economies-eligible-for-support-under-Gavi-MICs-Approach.pdf; "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

^{39 &}quot;Gavi's Approach to Engagement with Middle-Income Countries," Gavi, the Vaccine Alliance, September 2022, https://www.gavi.org/sites/default/files/programmes-impact/support/Gavi-MICs-Approach-Overview.pdf.

⁴⁰ Raising Generation ImmUnity: The 2023 Mid-Term Review Report (Gavi, the Vaccine Alliance, June 2023), 29, https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf.

⁴¹ See Gavi's forecasted expenditure for the 5.0 strategic period in "Financial Update, including forecast," Gavi, the Vaccine Alliance, December 6–7, 2023, https://www.gavi.org/sites/default/files/board/minutes/2023/6-7-december/07%20-%20Financial%20Update%20including%20forecast.pdf; Total health expenditure for MICs from "Global Health Expenditure Database," WHO, last accessed February 2024, https://apps.who.int/nha/database.

⁴² For the full list of 46 countries eligible under the MICs Approach, see "List of Countries and Economies Eligible for Support under the MICs Approach as of 1 July 2023," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/sites/default/files/programmes-impact/support/Countries-and-economies-eligible-for-support-under-Gavi-MICs-Approach.pdf.

⁴³ Gavi states that these four countries have been selected to apply for targeted support to help mitigate backsliding in vaccine coverage, as of July 2022. See "Gavi's Approach to Engaging with Middle-Income Countries," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/gavi-mics-approach.

In addition, MICs that are classified as fragile or conflict-affected under Gavi's Fragility, Emergencies, and Displaced Populations Policy and are either former Gavi-eligible (e.g., Ukraine) or never Gavi-eligible (e.g., Lebanon, Venezuela) may also receive certain types of Gavi support. Specifically, an adapted version of the MICs Approach enables these countries access to financing for vaccine procurement. ⁴⁴ In addition to vaccine financing, these countries can also receive technical assistance as well as access Gavi prices, in instances where this support could generate savings and with the agreement of manufacturers.

Select MICs also have access to support for sustainable pricing for newer vaccines. More recently, Gavi and UNICEF SD have operationalized an innovative financing mechanism to leverage Gavi volumes to provide longer-term demand predictability to suppliers and help reduce barriers for countries to participate in UNICEF's pooled procurement mechanism. ⁴⁵ In addition, through arrangements that predate the MICs Approach, former Gavi-eligible countries also have access to "prenegotiated" Gavi-like prices under manufacturer price commitments (MPCs) for vaccines, such as PCV, HPV vaccine, and RV on a time-limited basis. ⁴⁶ As background, MPCs negotiated in 2015 with GSK, Merck, and Pfizer provide former Gavi-eligible countries with time-limited access to vaccine prices at levels comparable to prices available to Gavi-eligible countries. ⁴⁷ More recently, UNICEF long-term agreements for certain vaccines, including RV and PCV, provide access to Gavi-like prices to MICs that have transitioned. ⁴⁸ Finally, some vaccines

⁴⁴ Fragile and conflict-affected countries were added to the scope of Gavi's MICs Approach, with an envelope of up to 25 percent of the overall MICs Approach budget, through decisions at Gavi's June 2022 board meeting. See: "Annex C: Paragraphs reference in decision point (d) on the rules under which support could be provided to fragile MICs," Gavi, the Vaccine Alliance, June 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/22-june/09%20-%20Annex%20C%20-%20Paragraphs%20referenced%20in%20decision%20point%20D.pdf; "Gavi's Approach to Supporting Middle-Income Countries Facing Challenges Related to Fragility, Emergencies, and Displaced Populations," Gavi, the Vaccine Alliance, September 2022, https://www.gavi.org/sites/default/files/programmes-impact/support/Gavi-MICs-Approach-Overview-Fragility-Emergencies-Displaced-Populations.pdf.

⁴⁵ This mechanism provides support to non-Gavi MICs and serves as an adapted version of UNICEF's Vaccine
Independence Initiative (VII). More details are here: "Update on Development of Strategy for Middle-Income Countries,"
Gavi, the Vaccine Alliance, December 4–5, 2019, https://www.gavi.org/sites/default/files/board/minutes/2019/4dec/10%20%20Update%20on%20MICs.pdf; "Annex B: MICs Approach Engagement," Gavi, the Vaccine Alliance,
June, 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/22-june/09%20-%20Annex%20B%20-%20
Paragraphs%20referenced%20in%20decision%20point%20B%20as%20amended%20by%20the%20PPC.pdf.

⁴⁶ This support for prenegotiated prices preceded the MICs Approach that was approved in 2020. For example, in 2015, Gavi helped strike deals with select manufacturers to provide lower prices for some vaccines under certain conditions. Limited information is available in public documentation on the specifics of these agreements. See, for instance, "Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn.who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning. pdf?sfvrsn=cc0e5566_6&download=true; "Vaccine Pricing: Gavi Transitioning Countries," WHO, December 2017, https://www.linkedimmunisation.org/wp-content/uploads/2018/02/Vaccine-Pricing-for-GAVI-Transitioning-Countries-1.pdf.

^{47 &}quot;Update on Development of Strategy for Middle-Income Countries," Gavi, the Vaccine Alliance, December 4-5, 2019, https://www.gavi.org/sites/default/files/board/minutes/2019/4-dec/10%20-%20Update%20on%20MICs.pdf.

⁴⁸ The tenders for PCV and RV also incorporate volumes from other MICs with stated price ranges. For more details see: "PCV Vaccine Prices," UNICEF, last updated November 30, 2023, https://www.unicef.org/supply/media/20141/file/PCV-vaccine-prices-30112023.pdf; "Rota Vaccine Prices," UNICEF, Last updated February 22, 2024, https://www.unicef.org/supply/media/20851/file/Rota-vaccines-prices-22022024.pdf.

(e.g., pentavalent vaccine) are available for purchasing through UNICEF SD at price parity between Gavi and non-Gavi MICs. 49

The COVID-19 pandemic delayed operationalization of this support, especially for support to new vaccine introductions. ⁵⁰ The external evaluation assessing the operationalization of Gavi's 5.0 strategy indicates that related programs and investments under the MICs Approach were postponed by at least two years because of the pandemic. ⁵¹ As a result, there is little publicly available information to date to assess progress and impact under the MICs Approach.

Challenges and gaps with Gavi's current approach

There are several challenges and gaps associated with Gavi's support to MICs to date.

First, this support is relatively small-scale. The budget envelope dedicated to the MICs Approach (\$300 million) is small in comparison to the scope and scale of the challenges associated with introducing critical new vaccines and addressing inequitable coverage and challenges with backsliding in MICs. Although the programmatic support under the MICs Approach was intentionally designed to be context-specific and small-scale, the full extent to which Gavi has been able to leverage limited "catalytic" support to drive improvements in MICs is still up for debate. 52

Second, vaccine pricing support is also subject to conditionalities. For example, MICs' procurement methods and policies are primary criteria for eligibility across these agreements. These pricing agreements generally require that countries procure through UNICEF SD or PAHO's Revolving Fund. 53 Many countries are unable to procure through UNICEF SD because of factors such as laws that prevent the use of external procurement agents, industrial policies that favor procurement from local producers, and inability to meet UNICEF SD's prepayment requirement (though some

^{49 &}quot;DTP-HepB-Hib Vaccine Prices," *UNICEF*, last updated December 27, 2022, https://www.unicef.org/supply/media/15346/file/DTP-HepB-Hib-Penta-vaccines-prices-27122022.pdf; "Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn.who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning.pdf?sfvrsn=cc0e5566_6&download=true.

^{50 &}quot;Annex B: MICs Approach Engagement," Gavi, the Vaccine Alliance, June, 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/22-june/09%20-%20Annex%20B%20-%20Paragraphs%20referenced%20in%20decision%20 point%20B%20as%20amended%20by%20the%20PPC.pdf.

⁵¹ Sjoerd Postma et al., "Evaluation of the Operationalization of Gavi's Strategy through Gavi's Policies, Programmatic Guidance, and Use of Funding Levers," Euro Health Group, August 2023, https://www.gavi.org/sites/default/files/programmes-impact/evaluations/Evaluation-operationalisationFinal-report.pdf.

⁵² For initial updates on the MICs Approach, see "Gavi Alliance Programme and Policy Committee Meeting 24–26 October 2023," Gavi, the Vaccine Alliance, October 24–26, 2023, https://www.gavi.org/sites/default/files/committees/ppc/minutes/2023/PPC-2023-Mtg-02-Minutes-POSTED.pdf.

^{53 &}quot;Gavi MICs Approach Support Request Guidelines," Gavi, the Vaccine Alliance, April 2023, https://www.gavi.org/sites/default/files/programmes-impact/support/Gavi-MICs-Guidelines.pdf.

efforts under the UNICEF financing mechanism seek to address this barrier). ⁵⁴ As another example, GSK's agreements require that countries have introduced GSK products with Gavi support to be eligible following transition; by contrast, former Gavi-eligible countries that introduced a different manufacturer's product with Gavi support can still be eligible for lower pricing from Merck and/ or Pfizer if they elect to switch to Merck and/or Pfizer vaccines. ⁵⁵ Countries can request a particular vaccine product when applying for Gavi support to impact their future eligibility for these exceptional prices. However, analysis found few cases in which countries submitted requests—and, moreover, many countries were not aware of the multiple product presentations or their financial implications. ⁵⁶ As a result, many countries may be unintentionally disqualified from the lower pricing agreements.

Third, the agreements negotiated with manufacturers are limited in number, and their applicability can be unpredictable and uncertain for countries. 57

Finally, several forms of support tend to be time limited. Lower prices for the HPV vaccine, PCV, and RV, as part of the 2015 MPCs, may only be available to countries for a fixed duration. Further, the 2015 MPCs from Merck for HPV vaccine and RV and Pfizer for PCV are set to expire at the end of 2025. Similarly, UNICEF's current tenders for PCV and RV vaccines extend through 2024 and 2028, respectively. Countries such as Papua New Guinea, the Solomon Islands, and Lao PDR—which Gavi projects will transition in 2025—may transition as these agreements and tenders end and could face higher prices more quickly. Relatedly, GSK's 2015 agreements for PCV, HPV vaccine, and RV applied

^{54 &}quot;Immunization Financing: A Resource Guide for Advocates, Policymakers, and Program Managers," Results for Development, 2017, https://www.r4d.org/wp-content/uploads/Immunization_Financing_Resource_Guide_2017_ FULL.pdf.

Indeed, MICs that chose to self-procure vaccine rather than use a pooled procurement mechanism accounted for 54 percent of the total volume of vaccines procured (excluding COVID-19 vaccines) in 2021. See *Global Vaccine Market Report 2022: A Shared Understanding for Equitable Access to Vaccines*, WHO, May 8, 2023, https://www.who.int/publications/i/item/9789240062726.

^{55 &}quot;Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn. who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning.pdf?sfvrsn= cc0e5566_68download=true.

⁵⁶ Helen Saxenian, "Overcoming Challenges to Sustainable Immunization Financing: Early Experiences from GAVI Graduating Countries," *Health Policy and Planning* 30, no. 2 (2015), https://doi.org/10.1093/heapol/czu003; https://www.gavi.org/sites/default/files/document/2021/2020-PCV-AMC-Annual-Report.pdf.

⁵⁷ The 2015 pricing agreements are non-binding, meaning that manufacturers' willingness to offer a lower price as well as the exact price available to countries are subject to change, including in response to supply availability and inflation, among other factors. See "Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn.who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning.pdf?sfvrsn=cc0e5566_6&download=true.

^{58 &}quot;Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn. who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning.pdf?sfvrsn= cc0e5566_68download=true.

^{59 &}quot;PCV Vaccine Prices," UNICEF, last updated November 30, 2023, https://www.unicef.org/supply/media/20141/file/PCV-vaccine-prices-30112023.pdf; "Rota Vaccine Prices," UNICEF, Last updated February 22, 2024, https://www.unicef.org/supply/media/20851/file/Rota-vaccines-prices-22022024.pdf.

⁶⁰ Raising Generation ImmUnity: The 2023 Mid-Term Review Report, Gavi, the Vaccine Alliance, June 2023, 28, https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf.

for 10 years from the date a country transitions to Gavi's fully self-financing phase. ⁶¹ As a result, some countries may face higher vaccine prices before they are adequately prepared to pay for them. For example, Honduras and Bhutan, which became fully self-financing in 2015, may face higher prices as soon as next year—yet they are at moderate risk of debt distress, according to the World Bank. ⁶²

Gavi and UNICEF are continuing to advance efforts around pricing access, including by integrating a request for access to lower pricing for former Gavi-eligible countries that have transitioned to fully self-financing into UNICEF vaccine procurement tenders, such as those for PCV and RV.⁶³ Access to these vaccines will remain critical going forward, especially because recent UNICEF projections suggest that demand for these products will increase.⁶⁴

Section 3: Policy recommendations for rethinking Gavi's engagement with middle-income countries

Previous sections of this paper make the case that (1) Gavi may not be able to fully deliver on its mission without addressing the challenges facing MICs, including those not currently or never eligible for traditional support; and (2) Gavi's current support modalities for MICs are insufficient to meaningfully address the challenges they face. These premises imply an imperative for improving Gavi's support to MICs, but do not inherently point to actionable solutions given the constraints Gavi itself faces.

In a scenario where Gavi was unconstrained by financial resources and Secretariat capacity, it has several potential options, including the following:

• Expanded eligibility criteria for traditional support. With dramatically increased financial resources, Gavi could consider expanding eligibility for its traditional programmatic support (e.g., direct purchase of subsidized vaccines) to a wider group of MICs. Expanded eligibility could cover all vaccines, or perhaps only "newer" vaccines (e.g., PCV, HPV vaccine, RV) that have not been widely adopted among non-Gavi-eligible MICs. In the current donor

^{61 &}quot;Vaccine Pricing: Gavi Fully Self-financing & Accelerated Transition Countries," WHO, November 2018, https://cdn. who.int/media/docs/default-source/immunization/mi4a/factsheet_vacc_pricing_gavi_transitioning.pdf?sfvrsn=cc0e5566_68download=true.

⁶² Raising Generation ImmUnity: The 2023 Mid-Term Review Report, Gavi, the Vaccine Alliance, June 2023, https://www.gavi.org/sites/default/files/investing/funding/resource-mobilisation/MTR23_Report_FULL_eng.pdf; "Debt Sustainability Analysis," World Bank, last accessed December 4, 2023, https://www.worldbank.org/en/programs/debt-toolkit/dsa.

⁶³ See UNICEF tenders for PCV and RV: "PCV Vaccine Prices," UNICEF, last updated November 30, 2023, https://www.unicef.org/supply/media/20141/file/PCV-vaccine-prices-30112023.pdf; "Rota Vaccine Prices," UNICEF, last updated February 22, 2024, https://www.unicef.org/supply/media/20851/file/Rota-vaccines-prices-22022024.pdf. Also see related discussion in Helen Saxenian, "Overcoming Challenges to Sustainable Immunization Financing: Early Experiences from GAVI Graduating Countries," Health Policy and Planning 30, no. 2 (2015), https://doi.org/10.1093/heapol/czu003.

^{64 &}quot;Middle Income Countries: Vaccine Industry Consultation 2023," UNICEF, 2023, https://www.unicef.org/supply/media/18891/file/UNICEF-VIC2023-Session10-MICsupdate-UNICEF-2023.pdf.

and fiscal environment, however, this path is unlikely to be realistic, affordable, or desirable to Gavi's funders and board members. The additional financial requirements to expand Gavi eligibility are substantial, as expansion would greatly increase the number of children eligible to receive Gavi-subsidized vaccines. This expansion pathway is also likely to be a relatively inefficient use of Gavi funds, as MICs already spend far more on vaccination than the Gavi-eligible cohort. It is also not clear that manufacturers would necessarily agree to extend the current Gavi price if Gavi were purchasing on behalf of a much wider cohort, including wealthier MICs.

International and national advocacy for vaccination. Gavi already includes advocacy specifically, "galvanising political commitment for sustainable and equitable routine immunisation programmes and new vaccine introductions"—as a foundational building block of its MICs Approach. 65 However, to date, there is limited information as to how this focus has been operationalized at a programmatic level. With additional Secretariat resources and expertise in public relations/advocacy, Gavi could continue and expand its role in shaping attitudes toward vaccination at the international and national levels. Globally, Gavi could work to counter increased vaccine hesitancy and educate the broader public about the benefits of vaccination. Nationally, Gavi could deepen its publicfacing provaccine advocacy role, while also advocating directly to MIC government decision-makers to expand vaccination programs and introduce additional vaccines. The financial costs of such a role may be feasible, and these interventions could offer high leverage, as communications/messaging interventions can have broad reach and be highly cost-effective. However, there are two notable risks. First, effective advocacy and communication is highly context-dependent and difficult to do well, especially from a centralized Secretariat in Geneva. Heavy-handed or poorly targeted public-facing advocacy could easily backfire, further entrenching antivaccine attitudes and related conspiracy theories. Second, direct advocacy to national policymakers for additional vaccine introductions—in the absence of pricing/procurement support or appropriate health technology assessment and product selection—could lead to the purchase and use of vaccines that are locally inappropriate or cost-ineffective in partner countries given local affordability constraints.

However, for the reasons described above, these options may not fit entirely with Gavi's comparative advantage. They may also be unfeasible or undesirable in practice, or at the very least entail significant risks.

Instead, we believe expanding support to MICs to access more affordable prices for vaccines alongside shaping a forward-looking, *global* innovation agenda for vaccination is where Gavi can best

^{65 &}quot;Gavi's Approach to Engagement with Middle-Income Countries," Gavi, the Vaccine Alliance, September 2022, https://www.gavi.org/sites/default/files/programmes-impact/support/Gavi-MICs-Approach-Overview.pdf.

leverage its **comparative advantage** in market shaping and demand consolidation to drive **maximum impact** for global vaccination efforts within **limited/constrained resources**.

Based on these constraints and comparative advantages, we offer three recommendations for Gavi to operationalize broader engagement with MICs in its next strategic period ("Gavi 6.0," 2026–2030) and beyond. We urge Gavi's board to empower the Secretariat with the requisite authorities, resources, and mandate to enable the successful operationalization of these recommendations. In addition, there may be a future need to revisit Gavi's governance structure to reflect broader engagement with MICs, including through board representation.

At least initially, these recommendations could be seen as additional to Gavi's existing programmatic support under the MICs Approach. Although the MICs Approach remains nascent, further assessment and evaluation under the learning agenda may suggest Gavi adjust ambitions and reorient its engagement to focus less on programmatic support while further prioritizing the types of support detailed in the recommendations below. Gavi could also revisit these considerations amid ongoing discussions on how best to evolve its sustainability model, including the eligibility and transition policy, which could have consequences for Gavi's engagement in noneligible MICs. 66

Recommendation 1: For newer and costlier vaccines, facilitate opt-in framework agreements with centrally negotiated tiered pricing for an expanded cohort of MICs

To date, UNICEF, with support from Gavi, has facilitated favorable pricing commitments with manufacturers for certain vaccines for some MICs (see Section 2). These arrangements offer a fixed price per dose for all eligible countries. However, as discussed above, these arrangements have distinct conditions and are fairly limited in scope and coverage. First, for certain vaccines, Gavi-like prices are only available to former Gavi-eligible countries—and on a time-limited basis. Second, the negotiated prices accessible for other groups of MICs, including through the newly established innovative financing mechanism for instance, are only available to countries procuring directly through UNICEF SD; some governments may find this requirement practically or legally challenging (see Section 2).⁶⁷ Third, many existing arrangements are set to expire *either* in 2025 *or* 10 years after a country's final transition from Gavi. In either case, this means that many transitioned countries are set to face dramatically higher prices within the next five years if these arrangements are not renewed. Those that are poised to transition in the coming years may also not be able to benefit from

⁶⁶ For example, one possible knock-on effect of a revised eligibility and transition policy that slows down the pace at which countries transition to becoming self-financing from Gavi support would be to decelerate the "growth" of the impact opportunity in noneligible MICs.

⁶⁷ We do expect self-procuring countries to pay a price premium for doing so; offering no options for self-procurement will exclude several countries.

these arrangements if they lapse; for example, Gavi projects that Papua New Guinea, the Solomon Islands, and Lao PDR will transition in 2025.

We recommend that Gavi dramatically expand existing efforts by working via UNICEF to negotiate tiered pricing framework agreements with manufacturers, available to all MICs on an opt-in basis, with priority placed upon the newest and costliest vaccines (e.g., PCV, HPV vaccine, RV). To entice manufacturers, a key distinction in our recommended approach compared to past efforts is the use of *tiered pricing* within centralized price negotiations, wherein manufacturers can offer differential pricing to different categories of countries based on ability to pay, usually crudely proxied by GDP (gross domestic product) per capita level. Use of tiered pricing may attract additional manufacturers who would balk at expanding the Gavi preferential prices to most or all MICs, which would undercut existing sales and erode profit margins in those markets. However, given the low uptake of these vaccines across Gavi-ineligible MICs, there is a meaningful win-win opportunity for manufacturers to expand sales, attain higher volumes, and reach additional markets at profitable prices, while also offering locally affordable prices to countries that have not yet proceeded with new vaccine adoption.

⁶⁸ This recommendation is at least partially consistent with pre-COVID Gavi board documents (December 2019), which proposed an Innovative Financing Facility (now referred to as an "Innovative Financing Mechanism") for Gaviineligible MICs. According to the proposal, the facility would offer "long-term demand guarantees to suppliers and . . . liquidity for country-bridge financing to ensure short-term predictability and payment of invoices to suppliers by leveraging Gavi's financing capacities," under the auspices of long-term purchase agreements "in line with tiered pricing principles." At the time of writing, this proposed mechanism has reportedly been operationalized however there is no information available publicly and it remains too early to assess any potential impacts on price. See: "Update on Development of Strategy for Middle-Income Countries," Gavi, the Vaccine Alliance, December 4-5, 2019, https://www.gavi.org/sites/default/files/board/minutes/2019/4-dec/10%20-%20Update%20on%20MICs.pdf; "Annex B: MICs Approach Engagement," Gavi, the Vaccine Alliance, June 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/22-june/09%20-%20Annex%20B%20-%20Paragraphs%20referenced%20in%20decision%20point%20 B%20as%20amended%20by%20the%20PPC.pdf.

⁶⁹ In practice, many manufacturers use tiered pricing to set prices offered to different countries based on ability and willingness to pay, with the goal of optimizing overall revenue/profit across all markets. Likewise, Gavi, through its partnership with UNICEF, already influences tiered pricing through price negotiations at the lowest tier—for instance, those offered to the poorest countries procuring through UNICEF with Gavi financing. The substance of this recommendation, therefore, is not that tiered pricing itself would be a new strategy, but that Gavi and UNICEF could play a constructive role in facilitating lower prices at higher tiers, such as those offered to non-Gavi MICs. We also note that GDP per capita is a highly imperfect proxy for cost-effectiveness or affordability. See Kalipso Chalkidou et al., "Value-based Tiered Pricing for Universal Health Coverage: An Idea Worth Revisiting," Gates Open Research (2020), https://doi.org/10.12688/gatesopenres.13110.3. A more sophisticated iteration would tier pricing based not just on GDP per capita, but on the local value of a given vaccine. It is probably not feasible for Gavi to fully incorporate value-based tiered pricing into a centrally negotiated framework agreement, but Gavi should ensure that local value informs its negotiating posture, such as by ensuring that offered prices by the manufacturer are low enough to be locally cost-effective to target countries, and to support countries in conducting health technology assessments to confirm that is the case prior to vaccine purchase and rollout.

For these agreements to be broadly useful, negotiated pricing must be available to self-procuring countries, in addition to those procuring directly via UNICEF or other regional bodies.70 The framework agreements would not be legally binding in such cases, but instead offer a goodfaith umbrella that creates shared expectations for pricing based on countries' income levels. Manufacturers could also include provisions in the framework agreement to adjust prices, to a predictable and reasonable extent, for self-procuring countries; in such cases, price adjustments could account for increased payment risk, transaction costs, and shipping costs.71 For example, it is reasonable that a low-volume, self-procuring country with a poor credit rating would pay more per dose than a high-volume, A-rated country procuring via UNICEF, even if both countries had equivalent GDP per capita—and the framework agreement should lay out clear expectations for how these factors would affect available pricing. The recently operationalized innovative financing mechanism under the overarching MICs Approach also could help ease liquidity constraints for some self-financing countries that purchase vaccines via UNICEF SD.72 Alternatively, with donor support, Gavi could underwrite payment risk or offer payment guarantees on behalf of select self-procuring countries, potentially narrowly targeted to those countries currently in debt distress. In such cases, there would be no justification for pharmaceutical companies to charge additional price premia covering payment risk, even for self-procuring countries.

Recommendation 2: For future vaccines, facilitate opt-in market entry framework agreements with centrally negotiated tiered pricing for an expanded cohort of MICs

The previous recommendation addresses observed challenges with access to existing but relatively new vaccines, most notably for PCV, HPV vaccine, and RV. The observed shortcomings in access for these vaccines have materialized over the past decades since launch and now must be corrected. For future vaccines, we argue that a more proactive approach to market entry for all MICs—which Gavi is uniquely positioned to lead—could help preempt these challenges, facilitating broad, equitable, and affordable access on a far more rapid timeline. Specifically, for new vaccines, and building on the approach outlined in Recommendation 1, we recommend that Gavi facilitate opt-in market entry agreements with centrally negotiated tiered pricing for an expanded cohort of MICs.

⁷⁰ And could also be expanded to cover other mechanisms, including the pooled procurement platform recently approved by the African Union. See: "Africa CDC Spearheads Bold Move to Secure Africa's Health Future by Creating a 50 billion Dollar Medical Market," Africa Centres for Disease Control and Prevention, February 19, 2024, https://africacdc.org/news-item/africa-cdc-spearheads-bold-move-to-secure-africas-health-future-by-creating-a-50-billion-dollar-medical-market.

⁷¹ See discussion of these factors and their impact on pricing and procurement in Rachel Silverman et al., "Tackling the Triple Transition in Global Health Procurement," Center for Global Development, June 17, 2019, https://www.cgdev.org/better-health-procurement.

^{72 &}quot;Annex B: MICs Approach Engagement," Gavi, the Vaccine Alliance, June 2022, https://www.gavi.org/sites/default/files/board/minutes/2022/22-june/09%20-%20Annex%20B%20-%20Paragraphs%20referenced%20in%20decision%20point%20B%20as%20amended%20by%20the%20PPC.pdf.

This process should begin with a horizon-scanning exercise of the vaccine pipeline, identifying and prioritizing upcoming vaccine market entries that are likely to offer significant health benefit to at least some subset of LICs and MICs. (Potentially, Gavi could leverage existing horizon-scanning efforts rather than setting up a standalone exercise.) An obvious candidate for Gavi's attention, in this respect, is the M72/ASO1_E candidate vaccine against tuberculosis, which demonstrated almost 50 percent efficacy in a Phase IIb trial and is scheduled to conclude a larger Phase III trial by 2029.⁷³ The tuberculosis burden is highly concentrated in MICs; cumulatively, India, Indonesia, the Philippines, South Africa, China, Angola, Brazil and Thailand account for about half of estimated global tuberculosis mortality, but do not qualify for traditional Gavi support.⁷⁴ Other potentially relevant vaccine candidates with current or forthcoming market entry include those for malaria, dengue, respiratory syncytial virus (RSV), and chikungunya.⁷⁵

Once relevant forthcoming vaccines are identified, Gavi can use its industry connections and technical expertise in market shaping to help create conditions for successful vaccine introduction. A first step would be to convene and coordinate MICs to help aggregate and forecast demand, providing increased predictability and visibility to manufacturers, ideally in cooperation with other regional procurement platforms, including the PAHO Revolving Fund and the newly announced procurement mechanism of the Africa Centres for Disease Control and Prevention. From there, building on and learning from the COVAX experience, Gavi should assess MICs' interest to pool or aggregate collective demand and represent MICs (on an opt-in basis) in collective market entry negotiations with manufacturers, including negotiation of acceptable tiered pricing regimes.⁷⁶

As with Recommendation 1, Market Entry Framework Agreements would be most impactful if they allow for flexibility in procurement arrangements, as many countries cannot or will not procure via UNICEF. More flexible procurement arrangements could include direct self-procurement by national governments, as well as regional purchasing blocs or "buyers' clubs" that could be established and self-managed MIC coalitions. ⁷⁷ If countries opt to procure outside of UNICEF, however, the Market Entry Framework Agreements should offer indicative guidance on how pricing will be adjusted to

⁷³ Dereck R. Tait et al., "Final Analysis of a Trial of M72/AS01_E Vaccine to Prevent Tuberculosis," New England Journal of Medicine 381 (2019), https://doi.org/10.1056/NEJMoa1909953; "TB Research Tracker," WHO, last accessed March 22, 2024, https://tbtrialtrack.who.int/#/.

⁷⁴ Based on estimated mortality data for 2022 extracted from "Global Tuberculosis Report," WHO, last accessed March 22, 2024, https://www.who.int/teams/global-tuberculosis-programme/data.

⁷⁵ See analysis of the current vaccine pipeline, including vaccines in late stage trials: "Vaccines Europe Pipeline Review 2022," Vaccines Europe, 2022, https://www.vaccineseurope.eu/wp-content/uploads/2022/12/00663248_EFP-Vaccine-Innovation-Report-RGB.pdf.

⁷⁶ For example, see the following discussion of collective negotiation for a tiered pricing regime, including a consideration of differential pricing based on local cost effectiveness and affordability: Kalipso Chalkidou et al., "Blueprint for a Market-Driven Value-Based Advance Commitment for Tuberculosis," Center for Global Development, February 5, 2020, https://www.cgdev.org/publication/blueprint-market-driven-value-based-advance-commitment-tuberculosis.

⁷⁷ For further discussion, see Kalipso Chalkidou and Robert Hecht, "Why HTA and Pooled Purchasing Must Be at the Heart of Global Health Transitions," *Centerfor Global Development* (blog), January 23, 2020, https://www.cgdev.org/blog/why-hta-and-pooled-purchasing-must-be-heart-global-health-transitions.

account for smaller sales volumes, increased shipping costs, and additional payment risk, among other factors that might be relevant to manufacturers. 78

Recommendation 3: Support a global coordinating hub for the Immunization Innovation Agenda (CHIIA)

To date, Gavi's focus in supporting global vaccine innovation has centered around innovation to serve the countries in its portfolio, which does not always overlap with the innovation needs of MICs. With (relatively modest) additional Secretariat resources, Gavi should consider an expanded role for itself as founder and host of a new Coordinating Hub for the Immunization Innovation Agenda (CHIIA), broadly targeting vaccine innovations that would be helpful or in-demand across national income levels. The proposed hub, supported by Gavi alongside other partners like WHO and CEPI, would welcome membership from all countries, but focus on the collective needs of the broad LIC and MICS cohort. It would help cement Gavi's role as an advocate and facilitator of the *global* vaccine agenda, including innovation needs, instead of its current, more narrow focus on the cohort of Gavi eligible countries.

The proposed hub would have several practical functions. In its most modest form—as a purely coordinating body—it would work hand in hand with WHO to help collect and collate innovation needs and potential demand across countries, define and prioritize target product profiles, communicate vaccine innovation needs to funders and manufactures alike, and convene or offer a consultative body to funders who are considering significant new vaccine research intended to serve the health needs of LICs and MICs. More ambitiously, CHIIA also could serve as a mechanism to coordinate and consolidate LIC and MIC demands for vaccine innovations through Advance Market Commitments (AMCs) or other similar mechanisms. One such example would be the proposed Market-Driven Value-Based Advance Commitment (MVAC) mechanism, which specifically adapts

⁷⁸ The Market Entry Framework Agreements could link to and support ongoing efforts to diversify vaccine manufacturing, with a growing number of Gavi's vaccine suppliers based in LICs and MICs. In 2022, there were 19 manufacturers supplying prequalified Gavi-supported vaccines, with more than half based in LICs and MICs. In comparison, there were only five such manufacturers in 2001. See: "About Our Alliance," Gavi, the Vaccine Alliance, last updated November 24, 2023, https://www.gavi.org/our-alliance/about.

⁷⁹ Efforts to expand Gavi's support for scaling innovations for immunization and health systems, as outlined in a recent CGD blog, would allocate financing focused in Gavi eligible countries but these investments could have spillover benefits for MICs. See: Orin Levine, Janeen Madan Keller, and Morgan Pincombe, "A Bigger Role for Gavi in Scaling Innovations for Immunization and Health Systems," Center for Global Development (blog), March 8, 2024, https://www.cgdev.org/blog/bigger-role-gavi-scaling-innovations-immunization-and-health-systems.

the original features of AMCs to better meet the needs and capabilities of self-procuring MICs.⁸⁰ Short of binding commitments, CHIIA could facilitate nonbinding "model framework agreements" for desired innovative vaccines based on countries' expressed demand and willingness to pay.

In cost-effectiveness terms, the proposed hub could offer extremely high leverage, as it would help drive a unified innovation agenda and South-South cooperation on vaccination while requiring only modest financial resources (to support twice-yearly in-person convenings and supporting analyses) and technical Secretariat support (three to five full-time dedicated staff). We conservatively estimate that an annual budget of about \$5 million—under 2 percent of Gavi's budget for the MICs Approach—would be sufficient to fund CHIIA in its initial form, although additional resources eventually might be required to support subsequent programmatic interventions (e.g., future AMC- or MVAC-like mechanisms).

Conclusion

MICs are increasingly becoming ground-zero for undervaccination challenges. Moreover, the global landscape of under-immunization will likely look vastly different in the post–Sustainable Development Goals era. Gavi cannot advance its core mission and drive progress against global vaccination goals without rethinking its role in addressing the range of challenges facing these countries, including former Gavi-eligible MICs and never Gavi-eligible MICs. Gavi's current support modalities for MICs are insufficient to meaningfully address the scale and scope of the challenges in these countries. These premises imply an imperative for improving and expanding Gavi's engagement with MICs.

Gavi should seize the opportunity to use its next five-year strategic period, "Gavi 6.0," to operationalize broader engagement beyond the group of countries eligible for traditional support. Specifically, "Gavi 6.0" is an opportunity for Gavi to leverage its comparative advantage in market shaping and demand consolidation to drive maximum impact for global vaccination efforts, all within constrained resources.

⁸⁰ The MVAC concept is fully elaborated in Kalipso Chalkidou et al., "Blueprint for a Market-Driven Value-Based Advance Commitment for Tuberculosis," Center for Global Development, February 5, 2020, https://www.cgdev.org/publication/blueprint-market-driven-value-based-advance-commitment-tuberculosis. In short, it proceeds in four steps. First, a coalition of national governments (in this case facilitated via CHIIA) would identify an innovation they need, develop a target product profile, and calculate how much value the proposed innovation would offer to local health systems, contextualized with local affordability/cost-effectiveness thresholds. Second, based on the results of the prior assessments, governments in the coalition would make binding advanced purchase commitments (price and volumes), which would be underwritten/guaranteeing by a third-party development bank, thereby obviating the need for money to be set aside in advance. Third, based on these commitments, the private sector would invest in R&D to develop the desired vaccine innovation. Finally, once a vaccine is developed and approved, countries would fulfill their advanced commitments through routine annual purchasing according to the pre-set terms and deploy the innovative vaccines on behalf of their populations. (Unfulfilled commitments would be back-filled by the guarantor MDBs, who would in turn convert countries' outstanding liabilities to sovereign debt according to the previously agreed terms.)

Appendix A

TABLE A1. Breakdown of 108 MICs (classifications for FY 2024), data for most recent year

Country	FY 2024 World Bank Income Group°	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Bangladesh	LMIC	Transitioning by 2030	Accelerated transition		2,688	6.54	9,812		98	93	29,000	0.20	3,020	3.13
Côte d'Ivoire	LMIC	Transitioning by 2030	Accelerated transition		2,486	5.37	2,250		76	20	135,000	0.95	933	0.97
Djibouti	LMIC	Transitioning by 2030	Accelerated transition		3,136	3.86	97	Stagnation	59	48	7,000	0.05	25	0.03
Ghana	LMIC	Transitioning by 2030	Accelerated transition		2,204	4.28	3,283		99	84	9,000	0.06	905	0.94
Kenya	LMIC	Transitioning by 2030	Accelerated transition		2,099	4.59	5,018	Stagnation	90	56	73,000	0.51	1,468	1.52
Lao PDR	LMIC	Transitioning by 2030	Accelerated transition		2,054	3.49	511	Stagnation	80	55	20,000	0.14	163	0.17
Nigeria	LMIC	Transitioning by 2030	Accelerated transition		2,163	1.85	17,892	Stagnation	62	38	2,271,000	15.97	7,923	8.22
Papua New Guinea	LMIC	Transitioning by 2030	Accelerated transition		3,116	1.08	611	Contraction	36	25	136,000	0.96	254	0.26
São Tomé and Príncipe	LMIC	Transitioning by 2030	Accelerated transition		2,387	2.20	42	Stagnation	97	69	<200		6	0.01
Solomon Islands	LMIC	Transitioning by 2030	Accelerated transition		2,205	-0.70	75	Contraction	89	90	<500		21	0.02
Benin	LMIC	Not transitioning by 2030	Preparatory transition		1,303	6.16	457		76		74,000	0.52	476	0.49
Cambodia	LMIC	Not transitioning by 2030	Preparatory transition		1,760	3.94	2,031		85	69	25,000	0.18	321	0.33
Cameroon	LMIC	Not transitioning by 2030	Preparatory transition		1,563	2.92	1,735	Stagnation	68	44	231,000	1.62	951	0.99

TABLE A1. (Continued)

Country	FY 2024 World Bank Income Group ^a	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Comoros	LMIC	Not transitioning by 2030	Preparatory transition		1,485	1.94	81	Contraction	88	79	2,000	0.01	24	0.03
Congo, Rep.	LMIC	Not transitioning by 2030	Accelerated transition		2,649	-0.99	470	Contraction	78	34	31,000	0.22	179	0.19
Guinea	LMIC	Not transitioning by 2030	Preparatory transition		1,515	5.10	605		47	3	170,000	1.20	466	0.48
Haiti	LMIC	Not transitioning by 2030	Preparatory transition		1,748	-1.37	663	Stagnation	51	41	65,000	0.46	269	0.28
Kyrgyz Republic	LMIC	Not transitioning by 2030	Preparatory transition		1,655	2.61	476	Stagnation	90	95	15,000	0.11	158	0.16
Lesotho	LMIC	Not transitioning by 2030	Preparatory transition		970	-1.48	262	Contraction	87	75	5,000	0.04	60	0.06
Mauritania	LMIC	Not transitioning by 2030	Preparatory transition		2,065	2.93	412	Stagnation	76		24,000	0.17	153	0.16
Myanmar	LMIC	Not transitioning by 2030	Preparatory transition		1,149	-0.84	3,509	Stagnation	71	64	168,000	1.18	920	0.95
Nepal	LMIC	Not transitioning by 2030	Preparatory transition		1,337	4.47	1,961		90	87	30,000	0.21	610	0.63
Pakistan	LMIC	Not transitioning by 2030	Preparatory transition		1,589	3.72	9,971	Stagnation	85	79	431,000	3.03	6,375	6.61
Senegal	LMIC	Not transitioning by 2030	Preparatory transition		1,599	4.57	1,202		88	66	55,000	0.39	550	0.57

TABLE A1. (Continued)

Country	FY 2024 World Bank Income Group°	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Tajikistan	LMIC	Not transitioning by 2030	Preparatory transition		1,054	7.36	716	Stagnation	97	97	5,000	0.04	261	0.27
Tanzania	LMIC	Not transitioning by 2030	Preparatory transition		1,193	4.43	2,363		88	76	205,000	1.44	2,303	2.39
Zambia	LMIC	Not transitioning by 2030	Preparatory transition		1,457	2.84	1,467	Contraction	82	81	93,000	0.65	672	0.70
Zimbabwe	LMIC	Not transitioning by 2030	Preparatory transition		1,677	1.17	1,003		90	77	33,000	0.23	489	0.51
Algeria	LMIC	Never Gavi			4,343	0.74	9,037	Contraction	77	71	82,000	0.58	951	0.99
Argentina	UMIC	Never Gavi			13,651	0.23	47,304	Stagnation	81	93	81,000	0.57	629	0.65
Belarus	UMIC	Never Gavi			7,888	0.33	4,478	Contraction	98	98	2,000	0.01	89	0.09
Belize	UMIC	Never Gavi			6,984	3.63	124	Contraction	84	76	<1000		7	0.01
Botswana	UMIC	Never Gavi			7,739	3.23	1,184	Contraction	86	77	1,000	0.01	61	0.06
Brazil	UMIC	Never Gavi			8,918	1.52	163,160	Contraction	77	58	431,000	3.03	2,761	2.86
Bulgaria	UMIC	Never Gavi			13,974	2.87	7,193		91	87	3,000	0.02	58	0.06
Cabo Verde	LMIC	Never Gavi			3,754	2.52	146	Stagnation	93	86	<500		10	0.01
Colombia	UMIC	Never Gavi			6,624	3.35	28,723	Stagnation	87	84	64,000	0.45	730	0.76
Costa Rica	UMIC	Never Gavi			13,365	2.65	4,891	Contraction	95	75	1,000	0.01	61	0.06
Dominica	UMIC	Never Gavi			8,351	1.00	35	Stagnation	92	89			1	0.00
Dominican Republic	UMIC	Never Gavi			10,111	4.49	4,635		88	59	2,000	0.01	205	0.21
Ecuador	UMIC	Never Gavi			6,391	0.14	8,798		70	60	77,000	0.54	299	0.31
Egypt, Arab Rep.	LMIC	Never Gavi			4,295	4.86	19,632	Stagnation	97	96	73,000	0.51	2,465	2.56
El Salvador	UMIC	Never Gavi			5,127	2.15	2,792		75	58	24,000	0.17	101	0.11

TABLE A1. (Continued)

Country	FY 2024 World Bank Income Group°	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Equatorial Guinea	UMIC	Never Gavi			7,182	-2.49	418	Contraction	53	13	11,000	0.08	50	0.05
Eswatini	LMIC	Never Gavi			3,987	2.93	334	Contraction	97	77	<500		29	0.03
Fiji	UMIC	Never Gavi			5,356	0.27	231	Contraction	99	78	<200		18	0.02
Gabon	UMIC	Never Gavi			8,820	1.47	548	Stagnation	60		22,000	0.15	64	0.07
Grenada	UMIC	Never Gavi			9,689	0.47	63		77	68	<500		2	0.00
Guatemala	UMIC	Never Gavi			5,473	3.55	6,004	Stagnation	79	69	29,000	0.20	372	0.39
Iran, Islamic Rep.	LMIC	Never Gavi			4,670	1.38	34,514		99	98	12,000	0.08	1,204	1.25
Iraq	UMIC	Never Gavi			5,937	0.94	10,837	Contraction	93	97	12,000	0.08	1,192	1.24
Jamaica	UMIC	Never Gavi			6,047	0.54	1,053	Contraction	98	83	<500		33	0.03
Jordan	LMIC	Never Gavi			4,311	1.73	3,334	Stagnation	77	90	53,000	0.37	245	0.25
Kazakhstan	UMIC	Never Gavi			11,492	2.72	7,736	Stagnation	99	97	4,000	0.03	413	0.43
Kosovo	UMIC	Never Gavi			5,340	3.76							19	0.02
Lebanon	LMIC	Never Gavi				-9.30	1, <i>7</i> 18		67	59	10,000	0.07	84	0.09
Libya	UMIC	Never Gavi			6,716	-0.58			73	72	30,000	0.21	120	0.12
Malaysia	UMIC	Never Gavi			11,993	3.15	16,351	Contraction	97	96	5,000	0.04	511	0.53
Maldives	UMIC	Never Gavi			11,781	6.93	542	Stagnation	99	98	<100		7	0.01
Marshall Islands	UMIC	Never Gavi			6,225	2.72	32	Stagnation	86	54			1	0.00
Mauritius	UMIC	Never Gavi			10,256	0.93	734	Stagnation	95	93	<1000		13	0.01
Mexico	UMIC	Never Gavi			11,497	0.56	77,372	Stagnation	83	82	129,000	0.91	1,882	1.95
Micronesia, Fed. Sts.	LMIC	Never Gavi			3,714	-0.85	45	Contraction	69	38	<200		2	0.00
Montenegro	UMIC	Never Gavi			10,093	2.66	618	Stagnation	80	70	<500		7	0.01
Morocco	LMIC	Never Gavi			3,442	1.61	8,198	Stagnation	99	99	6,000	0.04	651	0.68
Namibia	UMIC	Never Gavi			5,031	0.64	1,155	Contraction	84	79	7,000	0.05	69	0.07
North Macedonia	UMIC	Never Gavi			6,591	1.67	1,179		84	89	2,000	0.01	20	0.02

TABLE A1. (Continued)

Country	FY 2024 World Bank Income Group°	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Palau	UMIC	Never Gavi				-4.92	37		94	85			0	0.00
Paraguay	UMIC	Never Gavi			6,153	1.21	3,209	Stagnation	69	53	24,000	0.17	138	0.14
Peru	UMIC	Never Gavi			<i>7</i> ,126	2.29	13,898	Stagnation	82	54	41,000	0.29	594	0.62
Philippines	LMIC	Never Gavi			3,499	3.25	23,138		72	64	637,000	4.48	2,485	2.58
Russian Federation	UMIC	Never Gavi			15,271	1.18	135,778	Stagnation	97	97	41,000	0.29	1,397	1.45
Samoa	LMIC	Never Gavi			3,746	-2.33	58	Stagnation	76	45	<200		6	0.01
Serbia	UMIC	Never Gavi			9,538	3.64	6,316		92	89	2,000	0.01	68	0.07
South Africa	UMIC	Never Gavi			6,766	0.49	34,666	Stagnation	85	87	147,000	1.03	1,177	1.22
St. Lucia	UMIC	Never Gavi			13,031	1.20	105	Stagnation	81	63			2	0.00
St. Vincent and the Grenadines	UMIC	Never Gavi			9,125	1.16	47	Stagnation	92	94	<100		1	0.00
Suriname	UMIC	Never Gavi			5,859	-1.97	183	Contraction	77	51	2,000	0.01	11	0.01
Thailand	UMIC	Never Gavi			6,910	0.87	26,089		97	87	6,000	0.04	644	0.67
Tonga	UMIC	Never Gavi				-0.31	30		99	99	<100		2	0.00
Tunisia	LMIC	Never Gavi			3,747	0.45	3,255		97	98	2,000	0.01	197	0.20
Türkiye	UMIC	Never Gavi			10,675	4.53	37,391		99	94	12,000	0.08	1,245	1.29
Tuvalu	UMIC	Never Gavi			5,222	2.68	12		91	89			0	0.00
Vanuatu	LMIC	Never Gavi			3,231	0.73	42	Contraction	68		2,000	0.01	9	0.01
West Bank and Gaza	UMIC	Never Gavi			3,789	0.44			98	93	1,000	0.01	145	0.15
Bhutan	LMIC	Former Gavi		2015		0.86	94		98	97	<200		10	0.01
Honduras	LMIC	Former Gavi		2015	3,040	2.81	2,610	Stagnation	78	70	43,000	0.30	217	0.22
Mongolia	LMIC	Former Gavi		2015	5,046	3.09	1,056		95	93	2,000	0.01	72	0.07
Sri Lanka	LMIC	Former Gavi		2015	3,354	-1.37	3,618	Stagnation	98	98	6,000	0.04	306	0.32
Indonesia	UMIC	Former Gavi		2016	4,788	3.43	43,976		85	67	571,000	4.02	4,496	4.66
Kiribati	LMIC	Former Gavi		2016	1,702	2.14	34	Contraction	91	68	<200		4	0.00

TABLE A1. (Continued)

Country	FY 2024 World Bank Income Group ^a	Status of Gavi Eligibility	2024 Gavi Phase (Where Relevant)	Year of Transition From Gavi Support (Where Relevant)	GDP Per Capita (USD) ^b	Average GDP Growth Over Past 5 years (%)	Current Health Expenditure (USD Millions) ^b	World Bank Projection of General Government Expenditure (GGE) Per Capita ^b	DTP3 Coverage (%) ^b	MCV2 Coverage (%) ^b	Number of Zero Dose Children ^b	Share of Global Zero Dose Children (%)°	Total Births (Thousands)	Share of Total MIC Birth Cohort (%)
Moldova	UMIC	Former Gavi		2016	5,714	1.65	1,061		88	93	4,000	0.03	38	0.04
Angola	LMIC	Former Gavi		2017	3,000	-0.68	2,214	Contraction	42	25	614,000	4.32	1,339	1.39
Armenia	UMIC	Former Gavi		2017	7,018	4.80	1,710		93	94	1,000	0.01	34	0.03
Azerbaijan	UMIC	Former Gavi		2017	7,762	1.99	2,569	Stagnation	83	91	12,000	0.08	127	0.13
Bolivia	LMIC	Former Gavi		2017	3,600	1.48	3,297	Stagnation	69	49	65,000	0.46	264	0.27
Cuba	UMIC	Former Gavi		2017		-1.17			99	99	<1000		100	0.10
Georgia	UMIC	Former Gavi		2017	6,675	4.78	1,567		85	78	2,000	0.01	50	0.05
Timor-Leste	LMIC	Former Gavi		2017	2,389	7.89	178	Contraction	86	78	4,000	0.03	33	0.03
Vietnam	LMIC	Former Gavi		2019	4,164	5.65	16,818		91	81	114,000	0.80	1,463	1.52
India	LMIC	Former Gavi		2021	2,411	4.16	104,211		93	90	1,126,000	7.92	23,114	23.97
Nicaragua	LMIC	Former Gavi		2021	2,255	1.21	1,357	Stagnation	92	99	8,000	0.06	141	0.15
Uzbekistan	LMIC	Former Gavi		2021	2,255	5.39	5,357		99	99	8,000	0.06	803	0.83
Albania	UMIC	Former Gavi				3.31	1,327		97	93	<1000		29	0.03
Bosnia and Herzegovina	UMIC	Former Gavi			7,569	3.04	2,262		75	60	4,000	0.03	28	0.03
China	UMIC	Former Gavi			12,720	5.28	956,082		99	99	107,000	0.75	10,882	11.29
Turkmenistan	UMIC	Former Gavi			8,793	3.06	3,585	Contraction	98	99	1,000	0.01	137	0.14
Ukraine	LMIC	Former Gavi			4,534	-4.54	16,019		73	69	72,000	0.51	336	0.35

Notes: (a) LMIC = lower-middle-income country. UMIC = upper-middle-income country. (b) Cells are left blank where data is not available. (c) Cells are left blank where precise estimates of the number of zero-dose children are not available.

Sources: FY 2024 World Bank income groups from "World Bank Country and Lending Groups," World Bank, last accessed March 22, 2024, https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups. 2024 Gavi eligibility from "Eligibility," Gavi, the Vaccine Alliance, last accessed March 22, 2024, https://www.gavi.org/types-support/sustainability/eligibility. 2022 GDP per capita from "GDP per capita (current US\$)," World Bank, last accessed March 22, 2024, https://data.worldbank.org/indicator/NY.GDP.PCAP.CD. GDP average growth rate calculated for 2018–2022 from "GDP growth (annual %)," World Bank, last accessed March 22, 2024, https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG. 2021 health expenditure from "Global Health Expenditure Database," World Health Organization, last accessed February 2024, https://apps.who.int/nha/database. GGE per capita projection from Christoph Kurowski et al., "From Double Shock to Double Recovery, Technical Update 2: Old Scars, New Wounds," World Bank, September 2022, https://openknowledge.worldbank.org/server/api/core/bitstreams/76d5786b-9501-5235-922acaa71f99f0fc/content. DTP3 and MCV2 coverage from 2022 from "Input to the WHO/UNICEF Estimates of National Immunization Coverage (WEUNIC)," World Health Organization, July 17, 2023, https://www.who.int/publications/m/item/wuenic_input. Number and share of zero-dose children from 2022: "WUENIC Analytics," UNICEF, last accessed March 22, 2024, https://unicef-dapm. shinyapps.io/wuenic-analytics-2023/. Number and share of birth cohort from 2021: "World Population Prospects 2022," United Nations Department of Economic and Social Affairs, Population Division, 2022, https://population.un.org/wpp/Download/Standard/MostUsed/.