

Report of the Chief Executive Officer

19 June 2023

Dear Board members,

As I write this report – my last of 24 such reports – I am reflecting on the past 12 extraordinary years. I am humbled by the incredible accomplishments of the countries with which we work, the Alliance partners, and our talented and dedicated staff here in the Secretariat. It has been the honour of my professional life to contribute to this important work alongside such inspirational colleagues. I also want to thank you, our Board, for the trust you have put in the Alliance, the Secretariat and me over these years. I am deeply grateful for my time here and with you all, and I have tremendous excitement and optimism for Gavi's future. I am looking forward to welcoming Dr Muhammad Pate officially and in person at our meeting in a week's time.

Since its inception, Gavi has helped vaccinate more than 1 billion unique children. And if we add up Gavi's support to countries for routine immunisation, preventive campaigns, stockpiles for outbreak response and through COVAX, Gavi has supported over 6 billion completed vaccinations and more than 700 vaccine launches – which has led to a 70% reduction in vaccine-preventable child deaths in Gavi-supported countries, contributing to a more than 50% reduction in under-five child mortality. Over the course of the past 12 years alone, based on data from 2011-2022 (noting 2022 data is preliminary), Gavi-supported countries have vaccinated over 741 million unique children, averted 13.5 million future deaths, and yielded economic benefits of US\$ 177.7 billion. In addition, 19 countries have transitioned out of Gavi support. But it has not been easy. Each vaccine, each programme, each decision was analysed and debated – but with the understanding that often the biggest risk was the one posed by inaction.

On that note, and as is customary, I will use this report to dive into the busy past six months. This is another critical year for Gavi. Some of us call it "the year of delivery", and it was also referred to at our last Board meeting as "the year of renewal". This year is also obviously an important year of transition, and we have been making important appointments as we move to a more steady-state organisation following our intense work period over the last three years – including welcoming two new Managing Directors: Derrick Sim for Vaccine Markets & Health Security; and, just this month, Kelechi Ohiri for Policy, Programme Design & Delivery Support. We have also elevated and redefined two key roles as part of our operational excellence journey, welcoming Laura McKeaveney as Chief People & Experience Officer and Maria Thestrup as Chief Risk Officer.

With the Public Health Emergency of International Concern (PHEIC) ended for both COVID-19 and mpox, a transition to this more steady state is welcome. However, this



is not to say that the complexity is waning. This year is also a year of "poly-crises": ongoing COVID-19 infections, climate shocks becoming a common phenomenon, devastating wars, financial shocks, an increase in vulnerability, and – not unrelated – an uptick in outbreaks.

Many of you were with us last week in Spain, where the Government of Spain hosted our Mid-Term Review (MTR). We are grateful to the Government of Spain for their generous hospitality as a long-standing supporter of Gavi that has increased its support in the past years. During the event, together we took stock of Alliance progress against the objectives we set in the 2021–2025 Investment Opportunity; and took the time to reflect on what lies ahead for Gavi implementing countries, donors, Alliance partners, private sector and civil society. I encourage you to read the <u>MTR Report</u>. A special thanks to the many partners who stepped up and announced further support for Gavi, including a significant pledge from the Republic of Korea; the next stage of our front-loading facility with the European Investment Bank (EIB); and private sector partners of the Gavi Matching Fund, with support from the Netherlands, the United Kingdom and the Bill & Melinda Gates Foundation.

After the Board approval of the Gavi 5.1 strategy in December 2022, the Gavi Secretariat and Alliance partners are focused this year on delivering on Gavi 5.1, particularly on our four "must-wins": restoring routine immunisation and reaching zerodose children; revitalising the HPV vaccine programme; launching the malaria vaccine programme; and transitioning to a more routinised COVID-19 vaccine programme - a key topic up for decision at this Board meeting. We are also focused on how we work, including importantly the health of our Alliance.

Progress on our 2023 "must-wins"

We have articulated four "must-wins" for the year – of course, these are not the only priorities on which the Secretariat is focusing, but rather the narrowed list of issues on which we must make marked progress in 2023. The first is to **restore routine immunisation and reach zero-dose children**. As you all know, there were 3.2 million more zero-dose children in 2021 than in 2019 in Gavi-supported countries - due primarily to the pandemic, but also owing to other factors (e.g. health care worker strikes in DRC (Democratic Republic of the Congo), conflict in Ethiopia).

While 2022 WUENIC data will only be released mid-next month, preliminary analysis for the Mid-Term Review based on administrative data from countries representing about three quarters of the Gavi birth cohort shows encouraging signs of recovery in routine immunisation, with DTP3 coverage expected to have increased by approximately 3 percentage points (uncertainty range of 2-4 percentage points) across Gavi-supported countries between 2021 and 2022. This increase is driven in part by progress in High-Impact Countries, and we will confirm and unpack all these numbers once the WUENIC data is released in July. For now, it is an encouraging signal of recovery; but there is a lot more to do to get back on track for our Gavi 5.0 2025 targets and Immunization Agenda 2030 targets.



Firstly, we need to ensure those children missed during the pandemic are caught up, as many catch-up immunisation activities were delayed. During World Immunization Week, Alliance partners launched "The Big Catch-up" to advocate for and support countries to accelerate efforts to immunise children missed since 2019. Secondly, we need to accelerate implementation of the zero-dose agenda, given that roll-out of zero-dose programming was delayed in many countries during the COVID-19 pandemic. Given that 87% of the children missed since the pandemic began would have been zero-dose even without the pandemic - and are now the older siblings of today's zero-dose children - these two priorities are closely aligned.

This will be a record year for Gavi in terms of new programming, with countries expected to submit more than 40 Full Portfolio Planning (FPP) and Equity Accelerator Fund (EAF) applications - important progress for our zero-dose ambition, noting that the purpose of the EAF is to provide dedicated resourcing to reduce the zero-dose burden in lower-income countries by investing in targeted initiatives. The good news is that to date we are seeing a high approval rate, with 17 of 19 applications approved by Gavi's Independent Review Committee (IRC) on first review - indicating that countries are developing relevant plans of high quality. We are also seeing progress on some of the key shifts we identified as central to our zero-dose agenda (e.g. demand, gender, CSO engagement), but there is need for further improvement.

The next step will be to ensure robust implementation of these plans. Disbursement and utilisation of Gavi cash grants are at record highs in absolute terms. However, in 2022, as countries prioritised COVID-19 response and rapidly accelerated implementation of COVID-19 vaccine Delivery Support (CDS), health system strengthening (HSS) utilisation slowed; and EAF applications stalled. With most countries due to have EAF funding approved in 2023, after discussions at the Programme and Policy Committee (PPC) meeting last month, the PPC is recommending to the Board that it extend the timeline to disburse and use the remaining EAF envelope from end 2025 to end 2027 - noting that this does not change programme and use the funds. We are also planning to extend the implementation timeline for CDS to 2025 to enable countries to appropriately balance implementation of zero-dose and COVID-19 programming over other Gavi 5.1 priorities. This is about readjusting the different envelopes that exist to make sure that country absorption can match the envelopes of different funds.

Within the EAF envelope, the Zero-Dose Immunization Programme (ZIP) was established with US\$ 100 million subsequently granted to World Vision and International Rescue Committee to implement cross-cutting work in 11 countries across the Sahel and Horn of Africa. The focus of ZIP is impact at scale in reaching children beyond national immunisation programmes to include areas of conflict, cross-border settings and outreach to displaced populations; and to test and learn through this project as a new model for Gavi. Following a three-month inception phase, partners have proceeded to implementation, with detailed workplans and budgets approved; and US\$ 59 million is being disbursed for outreach activities from 2022-June 2024 (and the balance thereafter).



The second of our must-wins is a **revitalisation of our HPV vaccine programme**. Our ambitious goal is to reach 86 million girls by 2025 with HPV vaccines. In Gavieligible countries in 2023, 4 new routine introductions and 7¹ multi-age cohort (MAC) vaccination campaigns are planned, building on 29 routine introductions and 11 MACs since inception of the HPV vaccine programme in 2012. In addition, the Alliance expects at least three countries to submit HPV vaccine applications in 2023, with technical assistance from Gavi. The capacity of WHO and UNICEF has been bolstered by providing an additional approximately US\$ 6 million in PEF Foundational Support (FS) at global and regional levels, with an understanding that WHO country offices will be sufficiently primed to provide relevant technical support to countries, especially on matters relating to schedule switches from two doses to a single dose.

Strategic engagement with civil society organisations (CSOs) is underway at subnational, national and regional levels, focusing on building communities' trust and active demand for vaccines; increasing social and political commitment for HPV vaccine programme revitalisation efforts; and complementing service delivery as needed. Further, the Gavi Secretariat will engage CSO and Alliance partners in the development and implementation of a global advocacy strategy to support these efforts. A dedicated measurement framework has been developed in consultation with partners to enable comprehensive monitoring of progress across the Secretariat and partners against intended goals. Programme design and initial planning for US\$ 15 million to support the HPV vaccine learning agenda in up to five priority countries has been initiated. Furthermore, the MICs Approach continues to support both former and never Gavi-eligible countries to introduce HPV vaccines, with over five applications for support anticipated in 2023. A cross-Alliance group continues to provide strategic guidance on policies, decision-making, planning and implementation. In parallel, the Secretariat has simplified internal processes to accelerate programming, drawing on lessons from previous HPV vaccine implementation; COVAX; and early work on EVOLVE, our business transformation project to improve Gavi's end-to-end grant management. Finally, an updated Market Shaping Roadmap for HPV vaccine will be completed in 2023.

We are also in the early stages of **launching our malaria vaccine programme** - our third must-win. The IRC has so far recommended approval of 14 country applications (the three countries that participated in the MVIP plus 11 other countries), a critical milestone in the launch of the programme. Three more applications (Central African Republic, Nigeria and South Sudan) have been received and will be reviewed by the IRC at the end of the month.

Malaria vaccine supply constraints persist, with the 18 million doses available in 2023–2025 falling far short of country demand. A contract for supply of the world's first malaria vaccine was awarded by UNICEF Supply Division (SD) to the supplier (GSK) in summer 2022. However, the dose volumes available are insufficient to meet even the phase 1 needs of all 14 countries that now have IRC-approved applications.

¹ The seventh planned MAC, in Cambodia, has been expanded to a nationwide MAC per country preference, therefore delaying the 2023 introduction.



The Alliance has been working hard to improve the outlook for the malaria vaccine market. Having published the first Malaria Vaccine Market Shaping Roadmap in January 2023, efforts are underway to accelerate access to additional supply and improved pricing through both a second vaccine (R21/MatrixM) that is currently undergoing WHO policy and prequalification (PQ) review; and via a product transfer of RTS,S to a lower-cost manufacturer. All Alliance processes, including WHO recommendation and PQ, are being prioritised and accelerated. UNICEF SD is also undergoing tendering with both pipeline and current vaccine manufacturers to ensure supply will be available at the time of WHO recommendation and PQ. Both the RTS,S and R21 vaccines are undergoing in country regulatory registrations by their respective manufacturers - a critical step needed for country access and UNICEF procurement - with the first R21 registrations announced in April in Ghana and Nigeria.

To ensure complementarity of malaria vaccines with other prevention interventions, WHO and the Gavi Secretariat are co-leading coordination efforts across immunisation and malaria partners, including the Global Fund and USAID-PMI. This includes, for example, ensuring coordinated technical assistance to countries to develop quality vaccine funding applications; the inclusion of Global Fund Technical Review Panel members in the IRC review of malaria applications; and the development of a robust learning agenda.

The fourth must-win is the transition from the emergency state of COVID-19 vaccination to a more integrated and targeted COVID-19 vaccine programme. As we will discuss in more detail during our Board meeting, a key priority for this year is to support countries as they continue their COVID-19 vaccination focused on protecting high-priority populations in accordance with the latest WHO SAGE guidance. Gavi and Alliance partners are working closely with countries on the integration of their vaccination programmes and taking into account the realities of their needs and demand, to update and inform our planning assumptions for the remainder of this year and into 2024–2025. As highlighted by the recently updated SAGE recommendation, it is critical to continue vaccinating these select populations with additional boosters.

In terms of results, 55% of the population across Gavi COVAX AMC countries have received their primary vaccination series, this is in comparison to 66% globally and 75% in high-income countries (where the percentage of elderly and other high-risk populations is substantially higher). For the 34 countries with less than 10% coverage identified for concerted support in January 2022, 28 countries have now surpassed 10%, more than 20 of which are exceeding 20%. Credit goes to countries that have ramped up their programmes to protect their people. The Alliance work with countries through the COVID-19 Vaccine Delivery Partnership (CoVDP) has also been important, generating political will at the highest levels as well as providing targeted assistance to these 34 lower-performing countries. The experience and learnings from how the Alliance can come together innovatively to support countries in their COVID- 19 vaccine delivery are being taken into Gavi's core work, including building political will, transparency and targeted support for countries. One lesson is that it will be critical to bundle delivery finance with the vaccines and have an Alliance-led



process, leveraging existing Alliance mechanisms at global and regional levels to avoid confusion and duplication for any future emergency response.

Protecting high-priority populations remains the main focus for 2023 and beyond. Gavi COVAX AMC countries have made progress with reaching these individuals, with now 82% of health care workers and 69% of older adults completing their primary series; however, a higher percentage of the elderly should be vaccinated, and disparities remains across countries. In addition, coverage with critical boosters for these populations is still very limited; and creating demand and incentivising data collection and reporting on boosters must be strengthened. We will have the opportunity during our meeting to discuss progress under COVAX, and next steps for COVID-19 support to countries as COVAX integrates into Gavi.

Delivering on these must-wins will be possible only through operational excellence at all levels of the organisation and the Alliance. In line with the ambitious operational excellence agenda, two enablers have been recognised as priorities this year in order to deliver on the must-wins. They cover both the "what" (simplification, integration, EVOLVE) as well as the "how" (culture & wellbeing, Alliance health) and are central to how we are approaching the work of delivering on the must-wins.

We have also had a series of initiatives since the beginning of the year targeted at improving Alliance health given the intense work on COVAX and our not meeting for nearly three years, with two retreats with core Alliance leaders and the Partnership Team meeting in Zambia that also mainly focused on this topic. Alliance health remains a critical priority central to our collective success. As an Alliance, we worked together more closely during COVAX than ever before - as the quotation goes, "It was the best of times, it was the worst of times" - and now need to move into more regular ways of working. The core Alliance leaders will be meeting for a third time directly following our Board meeting to align on next steps flowing from the Board decisions and to take stock on our four must-wins. We will also be launching an Alliance Health Survey later this year to further to inform our work in this critical area.

A year of poly-crises

As you will have seen, I provided a Board update a few weeks ago on the continuing conflict in Sudan. Given the impact of the hostilities on the national immunisation programme and its systems - and the increasing pressure being placed on the surrounding countries and their immunisation programmes - last month, the Secretariat declared Sudan and its bordering countries of South Sudan, Central African Republic, Chad and Ethiopia an emergency for Gavi. This requires us to be extra-responsive and agile, to exercise a greater risk appetite to allow us to respond meaningfully to the emergency at hand, by prioritising all meetings, requests, approvals and other areas of work as relevant. This declaration will remain in place for 12 months and will be reviewed after three months. At present, Gavi's country teams are working with in-country partners to assess the challenges, how they relate to immunisation coverage and how Gavi can work to fill those gaps. We expect more concrete requests to be presented by countries in the next weeks.



This conflict brings increased vulnerabilities for displaced populations who are forced to leave their homes and who may be unable to access immunisation and other essential health services leading to risks of outbreaks. Extreme climate events or climate shocks are also an increasing source of such vulnerabilities - as with the flooding in Pakistan and the earthquake in Syria - and we can only expect this to increase.

In 2022, Gavi supported 40 outbreak response vaccination campaigns. This represents a ~75% increase over 2021, primarily driven by measles and cholera and to a lesser extent, yellow fever. The trend is continuing in 2023, with 20 total requests already approved for emergency vaccine stockpiles (11 for cholera, 3 for yellow fever, 4 for measles and 2 for meningococcal). With regards to Zaire ebolavirus, two outbreaks were reported in 2022, with vaccines used as part of both responses. A fully replenished global stockpile is available in 2023, though no outbreak has been reported so far.

Despite the doubling of planned preventative measles/measles-rubella (M/MR) campaigns from 7 in 2021 to 14 in 2022, significant immunity gaps for measles persist, largely due to a decline in routine immunisation coverage and delays in conducting campaigns during the COVID-19 pandemic. This has contributed to an increase in the number of measles-susceptible children and outbreaks. Therefore, in May at its last meeting, the PPC supported an immediate effort to increase rapid deployment of measles vaccine preventative campaign activities, as well as enhanced routine immunisation catch-up and recovery activities. With guidance from the PPC and agreement by the Audit and Finance Committee (AFC) in relation to the risk element, we will also revisit the June 2021 Board risk appetite statement to reflect the current epidemiological context and temporary need for timely preventative campaigns to decrease the risk of large disruptive measles outbreaks in the short term, noting that in the longer term, it will be important to refocus on ensuring high-quality campaigns so that we can better reach the unreached and break the cycle.

In addition, 30 countries across five of the six WHO regions reported cholera cases or outbreaks in 2022. As of 1 June 2023, 25 countries continue to report cholera cases, 14 of them in the AFRO region. The most severe outbreak was declared in Malawi and has spread to Mozambique, Zambia and more recently Zimbabwe and South Africa. The risk of cholera transmission remains in several geographies following recent natural disasters (e.g. Syria earthquake) and climate-related events (e.g. cyclones in southern African countries, droughts in East Africa), which might be exacerbated by the arrival of El Niño. To date, 10.2 million doses have been shipped for emergency use in 2023 in 9 countries, and approximately 4 million doses are in their way to Kenya, Cameroon and Somalia for outbreak response.

Supply is very tight, but we have managed - thanks to close work with the manufacturers and Alliance partners - to progressively increase vaccine availability. In 2013, only half a million doses of OCV were used globally. In 2014, we began our support for the OCV emergency stockpile; over the past ten years, supply has increased 70-fold, putting us in a position where despite the large increase in demand



for outbreak response in the last two years, countries have so far received all approved doses for response campaigns. This has required maintaining production at maximum current capacity and the temporary adoption of a single-dose schedule for outbreak response following SAGE guidance. As we have discussed, while ensuring support for outbreak response we are also starting to support countries in moving toward preventive cholera vaccine use in cholera hotspots. At present, three countries (South Sudan, Ethiopia, Nigeria) have approved preventive vaccination, totalling 17 million doses. In addition, Gavi's funding window for multi-year phased preventive cholera vaccination campaigns is open as of January 2023. A few countries that are advanced in the development of their national cholera plan for control or elimination (NCP) are anticipated to apply in 2023, for implementation beginning in 2024, including the Democratic Republic of the Congo, Mozambique, Bangladesh, Kenya and Cameroon. Other cholera-endemic countries are also able to apply.

Oral cholera vaccine (OCV) production is operating at maximum scheduled capacity for 2023, which is approximately 37 million doses. Efforts are underway, notably through the activities laid out in the Alliance Market Shaping Roadmap for OCV, to substantially improve market health. Supply is expected to increase from 2024 onwards through increased production capacity of the main supplier; and the entrance of two new manufacturers in the next five years, including hopefully one based in Africa.

To allow better tracking of cholera and targeting of OCV, Gavi is planning to open a cholera rapid diagnostic test (RDT) procurement funding support window later this month. This cholera RDT procurement support should eventually allow a shift from testing driven by outbreaks to more steady testing between outbreaks: better and earlier detection of cholera cases before there are large outbreaks will allow for more efficient and effective use of limited vaccine supply; and more stable, predictable demand for manufacturers. This cholera diagnostic test procurement support builds on continued progress with yellow fever diagnostic procurement support. Last year, Gavi-funded yellow fever diagnostic test procurement support facilitated Kenya's identifying yellow fever in central Kenya for the first time, prompting vaccination efforts to protect vulnerable populations.

Also in 2022, Uganda had its first Sudan ebolavirus outbreak in ten years. Unfortunately, there is currently no licensed vaccine available to help respond to this strain of the virus. This is also the case for the recent Marburg outbreaks in Equatorial Guinea and Tanzania. With partners, we are looking at how to move faster and be better prepared to respond to such outbreaks; collectively, we have identified a key gap for which Gavi is seen as well placed to respond in collaboration with partners' response efforts. As we will discuss during our Board meeting, we are proposing to establish a Global Virtual Pooled Inventory (GVPI) of candidate vaccines, where reserves of candidate vaccines which are not yet licensed could be deployed, if shown to be efficacious, through expanded access during an outbreak, which would also help to generate important evidence in support of licensure. This approach would enable protection of high-risk individuals in line with emerging clinical data, with the goal of stopping a deadly outbreak before transmission is widespread, remembering back to



the dramatic spread in the large-scale 2014–2016 Ebola outbreak in West Africa. As part of our Advanced Purchase agreement, Gavi established stockpiles of investigational Zaire ebolavirus vaccine to fight outbreaks before the vaccine was licensed.

The recent Sudan ebolavirus and Marburg virus outbreaks provide the use-case for the proposed GVPI concept: as there are no investigational vaccines readily available for expanded access use as part of accelerated access to candidate vaccines for faster response to serious outbreaks. The GVPI concept has been developed in collaboration with many key partners - including CEPI, WHO and UNICEF, as well as the US Government's Biomedical Advanced Research and Development Authority (BARDA). The Gavi Secretariat is also working with partners on other enablers; and Alliance partners are moving forward with efforts such as pre-approving study protocols, pre-arranging with clinical trial sites and pre-approval of studies by ethics committees. Gavi is moving forward with this key contribution to a coordinated Alliance and partner response, for which the GVPI can play an instrumental role in providing early access to vaccines as soon as the clinical trials show benefit.

These outbreaks stress the importance of leveraging Gavi's unique attributes in service of a stronger collective response. As the global health architecture has significantly evolved to adapt to the changing environment, the Alliance is actively coordinating with countries, donors, and other international and regional organisations to align our contributions and shape the agenda. This includes through the G7, G20, UN High-Level Meeting on Pandemic Prevention, Preparedness and Response (PPPR) and World Health Organization-led processes underway to establish medical countermeasures platforms, and to develop and institutionalise a coordinated response to future pandemics. Here we are also exploring ways to leverage our existing suite of innovative financing tools for surge and contingency financing for future pandemic responses, incorporating day zero vaccine financing and delivery funding from the outset - key lessons from COVID-19. In addition, we are actively supporting vaccine manufacturing diversification; we are exploring the role of an Advance Market Commitment with a focus on regional manufacturing in Africa, to ensure the substantial number of new capital projects result in sustainable capacity for the long haul without damaging the effective vaccine ecosystem built over the last few decades. We are providing inputs toward the negotiations around a pandemic accord, through the Intergovernmental Negotiating Body (INB) under the framework of strengthening Health Emergency Preparedness, Response and Resilience (HEPR). Lastly, Gavi is also an Implementing Entity of the Pandemic Fund and has been working closely with other entities and countries to develop future proposals. These global discussions are shaping the future of the global health architecture, and the Secretariat's engagement is positioning the Alliance to successfully deliver on Gavi 5.1 and potential Gavi 6.0 priorities related to PPPR, to respond to the needs of countries.

In parallel to adapting to an increasingly complex and often fraught environment, we are supporting countries to resume vaccine introductions and will request guidance from the Board on opening a funding window for a hexavalent vaccine programme. In



November 2018, the Board approved in-principle support for whole-cell pertussis hexavalent vaccine (hexavalent), a combination vaccine that includes six antigens already covered by Gavi support - the five in pentavalent vaccine plus inactivated polio vaccine (IPV). This approval was subject to specific support conditions that are now evaluated as having been met based on current market information, and it has been determined that the value of hexavalent is commensurate with its financial implications (as well as providing advantages for polio eradication). Therefore, the PPC is recommending to the Board to open a funding window. Given the higher price point, this new vaccine highlights the importance of supporting country decision-making on which vaccines (and which product presentations) to introduce, as Gavi's vaccine portfolio expands in response to country demand.

Vaccines approved under the Vaccine Investment Strategy 2018 (VIS 2018) are also at an inflexion point as we contemplate the sequenced resumption of the three VIS 2018 vaccine programmes that were paused in 2020 due to the COVID-19 pandemic: DTP booster, hepatitis B birth dose and rabies post-exposure prophylaxis. The pause was not applied to cholera or multivalent meningococcal conjugate vaccines (MMCV) considering their outbreak potential and the fact that they built on existing Gavi supported vaccine programmes. RSV was also approved "in principle" however the products are not yet available and will need to be re-evaluated once we have updated information for updating the programme design. The PPC provided guidance on how to proceed with the introductions that were paused in a manner that doesn't divert resources from Gavi 5.1 core goals and objectives. An important discussion at the PPC was also on adopting an initial lower level of ambition for some of these programmes (such as hepB birth dose in out-of-facility deliveries) noting that some of these vaccines are delivered at time points outside the standard infant immunisation schedule. To achieve higher coverage and adopt a higher level of ambition would likely require substantial additional health system strengthening (HSS) for maximum impact, which the PPC does not advise at this time due to cost and bandwidth issues. Finally, we are also seeking your approval of the proposed longlist of Vaccine Investment Strategy 2024 (VIS 2024) vaccines; of the frameworks for evaluating these vaccines; and to undertake further analyses to assess the potential value of providing support to develop, strengthen and deliver vaccines at new touchpoints for specific target populations.

Over the past 18 months, the Alliance has been working to mitigate the impact of six supply disruptions affecting two rotavirus vaccine suppliers, resulting in seven countries being affected by stock-outs over the past 12 months - some brief, some lasting several months - causing an estimated 3 million children to miss their full rotavirus vaccine course. Several challenges within the Secretariat and the Alliance provided hard lessons to be learned, such as the need for clearer processes to ensure that stock-out risk is more immediately visible; countries to receive more effective technical assistance for rapid switch decisions, and associated procedures to be more agile, to minimise impact on immunisation continuity. To build on these lessons, the Alliance is delivering new tools and trainings on vaccine optimisation to National Immunization Technical Advisory Groups (NITAGs) to build awareness of alternative vaccine options and inform their timely decision-making and assessment; and the Gavi



Secretariat is finalising differentiated review processes for urgent switch requests. The Vaccine Alliance will continue work with partners (e.g. UNICEF SD, WHO) to apply other mitigation measures to avoid such situations in the future.

Challenging fiscal and macro-economic spaces

Despite rising debt levels and the worsening impact of the war in Ukraine, most Gavisupported countries maintained or increased domestic resources for co-financing of Gavi-supported vaccines in 2022. The vast majority (96%) of co-financing was paid again in 2022 from domestic resources, highlighting countries' continued commitment to immunisation financing, as well as the Alliance's joint efforts to engage governments on domestic financing for health.

In June 2022, the Board approved exceptional support for fragile middle-income countries as part of the Middle-Income Countries (MICs) Approach. Since then, Gavi has received formal proposals from both Venezuela and Lebanon; and has approved time-limited support for routine vaccines in both countries. Sri Lanka has also been approved as a fragile MIC. As mentioned in a recent Board update, I formally approved the Venezuela request, estimated at ~US\$ 28 million (including financial support to purchase vaccine doses and supplies through the PAHO Revolving Fund) for the eight essential antigens of the Expanded Programme on Immunization (EPI) to cover immunisation operations for one year; we are currently working with the government on the disbursement of these funds.

In the case of Lebanon, the government submitted a proposal requesting support for the financing of routine vaccines as part of their existing national immunisation programme. The request comprised funding for three years (2023–2025), covering: vaccine financing for routine immunisation and relevant technical assistance. I formally approved the support in February for two and a half of the requested three years, equivalent to ~US\$ 14 million; another donor covered the cost of the first six months of 2023, assuring Gavi remains the funder of last resort (per our policy). We are in the process of operationalising this support with the government and with partners.

The challenging macro-economic environment is also impacting high-income countries, as we have seen in the past months with the failure of two U.S. banks (Silicon Valley Bank and Signature Bank), as well as the takeover of Credit Suisse by UBS in Switzerland and First Republic Bank by JPMorgan Chase in the United States of America. The Gavi Secretariat is closely monitoring the situation, working with the Chairs of the AFC and Investment Committee; but so far, the risk to Gavi investments seems contained.

Continual learning and data-driven improvements

The current complex operating environment highlights the importance of Gavi maintaining a learning mindset and remaining flexible to course-correct based on available data. In this context, it is important to note the following key evaluations and assessments that are helping lay the foundation for improved ways of working going



forward. We have three key evaluations currently underway, including: (1) operationalisation of Gavi's policies, programmatic guidance and funding levers, to be completed later in 2023; (2) midterm evaluation of the Gavi 5.0 strategy; and (3) evaluation of Gavi's contribution to reaching zero-dose children and missed communities, and operationalisation of the <u>Zero-Dose Learning Hubs</u>.

We are pleased to share that the final report of phase 1 of the <u>independent COVAX</u> <u>evaluation</u> has now been published. The COVID-19 pandemic was an emergency of unprecedented proportions, and the world responded in an unprecedented way; COVAX was core to that response. This independent evaluation by Itad is so important because it helps us to independently collect results; learn from this incredible undertaking; and share critical insights into what worked well and also what worked less well. Of course, we didn't agree with everything in the evaluation, but we encourage you to read it, including our <u>management response</u>.

We also recently concluded the <u>independent evaluation of Gavi's Independent Review</u> <u>Committee</u> (IRC). Approximately 100 key informants from across the Alliance were engaged in the process to help us diagnose the main strengths and weaknesses of the IRC review process and to co-create a set of actionable solutions through a series of workshops. Key findings and recommendations were developed in six thematic areas, including: mandate; process design and operationalisation; protocols and tools; membership; and learning and impact. The evaluation confirmed the high value the IRC brings to the Alliance by ensuring the integrity and quality of our programming in line with Gavi's strategic objectives; and called for greater differentiation of the IRC process and review criteria by materiality and risk. The Secretariat is now working to implement these changes, with a focus on process design and operationalisation, over the coming months. As part of this, the Board will be asked at this meeting to approve a waiver of the independent review for a small set of country applications of low materiality and risk. We will revert with learnings and updates to the IRC mandate requiring a Board decision.

The Multilateral Organisation Performance Assessment Network (MOPAN) assessment is ongoing and will be published by end 2023; we anticipate the findings will serve as a useful tool to reflect on our operational effectiveness and performance. MOPAN is a network of 22 donor countries that join forces to conduct an in-depth analysis on an international organisation, looking closely at their internal processes and way of working. The last assessment of Gavi was conducted in 2015 and 2016; and we are looking forward to the results of this updated assessment.

Looking ahead

As this is my final Gavi Board meeting as CEO, I was reflecting on the role of the Board and its committees, and how things have evolved in my time with Gavi. The Vaccine Alliance has grown considerably over the last 12 years. We have made the case for Gavi as the best buy in global health, and our donors have supported vaccine equity through more than US\$ 38.3 billion in funding. We now have 19 antigens in our portfolio, 50 product presentations – we support routine immunisation, vaccination



campaigns and emergency stockpiles for outbreaks. Several vaccines are deployed in multiple ways. The rate of R&D has ramped up; and through the continued innovation by the pharmaceutical industry and researchers, we are entering a renaissance in vaccinology - and, generally, the complexity of the ecosystem, and of Gavi programmes, has done the same. Gavi is no longer the best kept secret in global health. This is a good thing overall. It means that we are digging in deep to find new ways to support countries through immunisation. This also requires more from the Secretariat, from each constituency and from you - things are not always as straightforward as they used to be, requiring ingenuity and innovation in how we deliver our important work.

As discussed at the Board retreat, long-term macro-contextual trends such as climate change, population growth and increasing fragility and conflicts continue to alter the Alliance's operating environment, with implications for both its current 5.1 agenda and the future strategy cycle. The recent Board retreat came at a pivotal time for the Board and the Alliance. It has been an opportunity for the Board to take a step back and reflect on how to come together to execute Gavi's important 5.1 mandate and start planning for Gavi 6.0. A critical piece of work that will kick off in earnest with Muhammad in the fall, through the Gavi 6.0 strategy design process. Conversations on these trends at the retreat helped surface key themes. They included the impact of climate change and the role of the Alliance supporting countries to mitigate and adapt to its consequences including on disease patterns; the evolution of Gavi's role in global health security, learning from COVAX and ongoing 5.1 work; how Gavi's eligibility, cofinancing and transition model may need to evolve; as well as the engagement in MICs, exploring our future vaccine agenda and implications for our HSS priorities: how Gavi will support countries in building new platforms beyond childhood vaccination, while doubling down on the zero-dose agenda. Finally, we explored how our operating and partnership models will need to continue to evolve to meet these changing needs, including how we want to better collaborate with other funders on the basis of improved results, and with new regional mechanisms and partners.

All of these factors are interconnected, and it makes for a complex picture. Yet this is not discouraging - against this backdrop, I have huge optimism for Gavi's path ahead. In 6.0, Gavi has the opportunity to take the learnings of the past 20+ years, and in particular the last intensive period, and put them to work for the countries we support. We have an exciting opportunity with VIS 2024 to potentially reduce neonatal mortality (which has grown as a proportion of under-five mortality in part through Gavi's success with other vaccinations) through the combination of RSV and Group B strep vaccinations. We are looking forward to scaling up malaria vaccines and, with the rate of R&D increasing, having new vaccines on the market. A tuberculosis vaccine may become available during the upcoming strategic period. And then, finally, perhaps in time we will be able to add an HIV vaccine to our roster. I trust the power of science and will never give up hope - particularly given all of the new breakthroughs in vaccinology, computing and immunology.

Gavi is already a central support to countries on their pandemic prevention, preparedness and response efforts. For example, during the PPC it was an



implementing country PPC member who leaned in and impressed upon others the value of being optimally prepared in the face of Ebola - and so the importance of the GVPI. The world goes through cycles of panic and neglect when it comes to pandemics and outbreaks, and there is certainly a desire to turn the page on COVID- 19. But in turning the page, we must remember to carry forward the critical work and lessons from this time so that for each successive vaccine-preventable outbreak or pandemic - whether brought on due to climate emergencies, increased contact with animals, vector ecology, conflict, migration or population density - we are in a better position than the last.

I want to end on the note of equity. This is the conviction on which Gavi was founded and is our continuing North Star. The pandemic may have taken us back, but together we are regrouping and continuing this important climb. I will forever remain one of the Alliance's greatest supporters and want to thank you all again for the honour of having served as Gavi's CEO these past 12 years. I look forward to seeing you next week.