

## **Gavi Alliance Programme and Policy Committee Meeting** **16-17 May 2023** **Global Health Campus, Geneva, Switzerland**

### **1. Chair's report**

- 1.1 Noting that the meeting had been duly convened and finding a quorum of members present, the meeting commenced at 09.00 Geneva time on 16 May 2023. Anne Schuchat, Programme and Policy Committee (PPC) Chair chaired the meeting.
- 1.2 The Chair welcomed all participants, in particular new members, including Adrien de Chaisemartin (Bill & Melinda Gates Foundation); Hanna Nohynek (Chair of the World Health Organization's Strategic Group of Experts on Immunization (SAGE)); Eduardo Humberto Retes (Implementing Governments - Honduras); and Alexandra Rudolph-Seemann (Industrialised Governments - Germany).
- 1.3 As the PPC Charter allows for any Board or Alternate Board Members to observe Committee meetings, the Chair welcomed the participation of Takeshi Akahori and Francesca Manno (Japan/Italy/New Zealand/Spain) who would be joining for parts of the meeting.
- 1.4 The Chair noted that regrets had been received from Roli Singh (Implementing Governments - India).
- 1.5 The Chair emphasised the ongoing endeavour to strengthen the link between the PPC and the Evaluation Advisory Committee (EAC), and welcomed James Hargreaves, Chair of the Evaluation Advisory Committee, who would attend parts of the meeting. She also advised the PPC that Kent Ranson had attended the EAC meeting in March 2023 and would continue to serve in a liaison role for the PPC at the next EAC meeting in October 2023.
- 1.6 She informed PPC members that Nestor Advisors Ltd had been retained as independent external consultants to guide a Board and Committee Evaluation process for Gavi. In this regard, she noted that two representatives would be observing the PPC deliberations. In this context she reminded PPC members to complete the evaluation survey which they would have received by email.
- 1.7 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).
- 1.8 The minutes of the PPC meetings of 31 October-1 November 2022 were tabled to the Committee for information (Doc 01b). The minutes had been circulated and approved by no objection on 3 January 2023.

- 1.9 The Chair referred to the PPC workplan (Doc 01c). Committee members were reminded that they may contribute to the workplan by raising issues with either herself or the Secretariat.
- 1.10 The Chair was pleased to note that the CSO constituency had made use of BoardEffect to post comments and questions prior to the PPC meeting. The Secretariat has been requested to ensure the issues raised are addressed during presentations.
- 1.11 She invited Kent Ranson to provide feedback from the EAC meeting. He highlighted several areas discussed by the EAC that he felt were relevant to PPC deliberations, including: i) a discussion on the Mid-Term Evaluation, for which the primary audience is the Board in preparation for Gavi 6.0; ii) a panel discussion on Gavi partnerships, which considered the extent to which partnerships should be treated in Gavi evaluation. The EAC had advised that partnership functioning is critical to the theory of change for all of Gavi's work, and as such, should be within the scope of evaluation, and that it would be important to involve partners early in evaluation planning, emphasise learning over accountability, and ensure evaluators are well briefed on the model; iii) the Zero-Dose Evaluation and Zero-Dose Learning Agenda, which is a large and impressive body of work that the PPC should be aware of in its discussions; and iv) more generally, the EAC's desire to strengthen links with PPC and ensure that evaluation questions are designed to address PPC needs.

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## **2. CEO Update**

- 2.1 Seth Berkley, CEO, welcomed the PPC to their first-in person meeting of the year, which would also be the thirtieth and last PPC meeting he would be participating in as Gavi CEO. He noted that this will be a special year for Gavi with emphasis on renewal, delivery and transition.
- 2.2 Dr Berkley briefed the PPC on the Gavi Mid-Term Review (MTR) which is scheduled to take place in Madrid, Spain on 13-15 June 2023, noting that the MTR represents an opportunity to take stock of the progress made by the Alliance against the objectives set in the 2021-2025 Investment Case.
- 2.3 Dr Berkley reported that the Secretariat and partners are focused on the delivery of Gavi 5.1. He provided detailed updates on the progress of 4 key must wins, namely: restoring Routine Immunisation (RI) and reaching zero-dose children; relaunching the human papillomavirus (HPV) vaccine programme; launching the malaria vaccine programme; and finally, driving and integrating the COVID-19 vaccine programme. Delivering on these must wins will be underpinned by operational excellence at all levels which is being led by the Chief Operating Officer, David Marlow.

- 2.4 He highlighted that this year has been a year of “poly-crises” and briefed the PPC on ongoing COVID-19 infections, climate shocks, devastating wars, financial shocks including in high-income countries, increase in vulnerability, and a surge in disease outbreaks including measles, cholera, and yellow fever.
- 2.5 Dr Berkley referred to plans to resume vaccine introductions, including opening a funding window for a Hexavalent vaccine programme which if recommended by the PPC, would be presented to the Board for decision during the Board meeting in June 2023, and resuming the four vaccine programmes from the 2018 Vaccine Investment Strategy (VIS) that were paused in 2020 due to the COVID-19 pandemic. He added that the PPC would also be requested to recommend to the Board a proposed longlist of pathogens for the VIS 2024 for more in-depth analysis.
- 2.6 In relation to transition at the Secretariat level, Dr Berkley highlighted the recruitment of new key senior staff, and noted that his successor, Dr Muhammad Pate, would be observing the upcoming Board meeting on 26-27 June 2023 before he officially takes office in August 2023.
- 2.7 With reference to continual learning and data-driven improvements, Dr Berkley underlined the importance of maintaining a learning mindset and outlined key evaluations and assessments that are helping to lay the foundation for improved ways of working including: i) the final report of phase 1 of the independent COVAX evaluation, ii) the independent evaluation of the Gavi Independent Review Committee (IRC), iii) the ongoing Board and Committee evaluation, and, iv) the Multilateral Organisation Performance Assessment Network (MOPAN) assessment of Gavi.
- 2.8 Finally, Dr Berkley concluded by sharing personal reflections on the role of the PPC which has evolved over time, noting that the PPC has been, and will continue to be, a critical governance body that provides expertise and advice on key programmatic and policy decisions to be put forward to the Board.

### *Discussion*

- The PPC thanked the CEO and expressed deep appreciation for his work and support to the PPC throughout his tenure, and highlighted the mark he has left on the PPC and Gavi Alliance on the whole.
- The PPC welcomed the flexibilities granted to countries to reallocate existing funds for catch-up and recovery plans, as well as the improved efficiencies through the EVOLVE project and IRC reviews. The need to focus on the big catch-up to reach the children who were missed during the COVID-19 pandemic, while restoring the performance of immunisation programmes to pre-pandemic levels was highlighted.
- With reference to concerns on new vaccines supply, the CEO explained that it is normal for new vaccines to have a slow start and be available in limited

quantities. Preparing countries for vaccine roll-out and maintaining vaccine-confidence by preventing stock-outs would be critical in this regard.

- The CEO acknowledged reflections from the PPC on the CEO transition noting, also as per his regular discussions with Dr Pate, that while it is important for the incoming CEO to be engaged in upcoming key decisions, it would be critical to continue delivering, making progress and maintaining Gavi's contribution to ongoing global initiatives.
- In reference to the PPC concerns on measles outbreaks and the urgency of putting in place prevention plans, the CEO reiterated the importance of improving the quality of campaigns and reaching missed children to prevent recurrent outbreaks.
- The CEO noted reflections by some PPC members on Health Systems Strengthening (HSS) related challenges, and highlighted the resilience that national immunisation programmes have demonstrated at country level during the COVID-19 pandemic.
- The CEO acknowledged PPC comments on the importance of focusing on Gavi's core mission, and providing the Board with clarity on trade-offs of key investment decisions notably the implications of taking a life course approach to immunisation, and requested more analysis on the topic. The CEO clarified that this would be a central part of the engagement with the Board on Gavi 6.0 through a series of planned deep dives. He further added that the focus on children under five is critical, while emphasising, that demographic transition and outbreaks require the Alliance's engagement and consideration for other age groups.
- Regarding the malaria vaccine, Dr Berkley acknowledged the cross-Alliance efforts to address the complexities associated with rolling out this vaccine.
- In responding to reflections on the value of the recently signed Memorandum of Understanding (MoU) with the African Union (AU) the CEO noted that the AU is a critical player with whom having a seamless partnership would be critical.

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### **3. COO Update and Read-Out from Audit & Finance Committee (AFC)**

- 3.1 David Marlow, Chief Operating Officer (COO), provided an update on the AFC meeting which had taken place on 11 May 2023. underlined a critical area for the consideration of the PPC in relation to the disbursement of cash programmes, and outlined key updates and topics that would be covered in the upcoming governance cycle.

- 3.2 Mr Marlow outlined financial forecast highlights for Gavi core budget as well as the COVAX Advance Market Commitment (AMC) noting the programmatic items for PPC consideration which have financial implications.
- 3.3 In relation to the Operational Excellence (OE) agenda, the COO provided a high-level view on progress across key dimensions of Gavi's performance and outlined examples of OE initiatives with programmatic impact. He noted the new Alliance Partnerships and Performance Team (APPT) as one critical OE initiative.
- 3.4 Finally, the COO concluded by updating the PPC on the EVOLVE project expected outcomes, and on the outcomes of the Partnerships Team retreat that took place in Zambia in March 2023.

#### *Discussion*

- The PPC welcomed the information provided by the COO on the balanced scorecard, and the overall operational excellence agenda.
- The PPC commended the focus on accelerating disbursements to countries as well as the cross-topic view provided by the COO, noting the need to accompany this with an overall view of the allocation of efforts and resources across the different programmes.
- In relation to the balanced scorecard, PPC members encouraged the COO to i) include a separate risk module, ii) explore better measures of transition preparedness risks, and iii) include percentages of the Health Systems and Immunisation Strengthening (HSIS) funds flowing through governments' systems.
- The COO welcomed the PPC input on the draft balanced scorecard noting that it is work in progress. The aim of the scorecard is to provide a tool for the Board and the Committees with an overall view on different modules to ensure transparency and foster trust between the management, the Committees, and the Board. He underlined that the scorecard should help guide the reader to focus on the right areas of interest and must not become too complex. He acknowledged reflections from the PPC on the cash disbursements, the Equity Accelerator Fund (EAF) and HSIS noting that these important topics would be discussed in detail under separate agenda items.
- Regarding the IRC processes, one PPC member noted that it would be critical to adapt and differentiate processes according to the different funding envelopes.
- One PPC member underlined the importance of having contingency plans and scenario planning in view of the latest financial markets disturbances.

- In reference to the Alliance health, the COO noted the PPC comments on the importance of having the Alliance partners onboard as countries prepare for the different vaccine rollouts, as well as the need to resume the discussions on the partners' roles, responsibilities and expectations.

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#### **4. Strategy, Programmes and Partnerships: Progress, Risks and Challenges**

- 4.1 Johannes Ahrendts, Director, Strategy, Funding and Performance provided an overview of the progress against the Gavi 5.1 strategic indicators outlined in the Gavi Balanced Scorecard (Doc 04).
- 4.2 Dr Ahrendts updated on new vaccine introductions and routine immunisations, noting the increase in vaccine-preventable diseases outbreaks due to COVID-19 disruptions and that the PPC was being asked to consider amending the risk appetite statement to support preventative campaigns.
- 4.3 He updated on Gavi's progress in supporting HPV and malaria vaccines, and noted the strong country demand to tackle the zero-dose agenda and there was now a need to seek an extension the Equity Accelerator Fund (EAF) to facilitate planning and implementation timelines aligned with the original intent of the EAF. He noted that co-financing had either been maintained or increased, despite rising debt levels experienced by countries.
- 4.4 Finally, Dr Ahrendts mentioned the external Independent Review Committee's (IRC) evaluation and outlined the proposals for which PPC guidance was requested.

#### *Discussion*

- The PPC supported the proposed recommendation to extend the EAF at no additional cost, noting this as an important show of support for countries facing heightened crisis and struggling to reach their zero-dose agenda goals.
- During the discussion on scaling up zero-dose agenda efforts, one PPC member emphasised the importance of country confidence in the expertise in organisations like the International Rescue Committee and World Vision, and stressed the need for close collaboration with local partners and governments, particularly as this was crucial for long-term success and achieving agenda ambition. The Secretariat explained it was exploring ways to assist countries in obtaining more vaccines and finding ways to provide support to countries experiencing financial difficulties and challenges.
- The PPC recognised a decline in vaccine confidence due to the COVID-19 pandemic and emphasised the need for an effective communication strategy,

particularly for reaching zero-dose populations and for introducing new vaccines.

- The PPC commended the progress in the HPV revitalisation programme, and encouraged focus on high population areas, whilst also ensuring that the programme includes all countries. Additionally, the PPC emphasised the need to allocate adequate resources to ensure successful implementation.
- The PPC requested that the October 2023 accelerated transition country reporting include an overview of all countries in accelerated transition, not just Nigeria and Papua New Guinea (PNG). This is especially important as two countries in accelerated transition, PNG and Timor-Leste, are currently facing challenges.
- Regarding SG4, and specifically the typhoid programme, one PPC member noted the slow programme progress with only four countries implementing the programme, and one country in application phase. They noted the pace affecting vaccine supply and programme sustainability and encouraged Secretariat involvement in both country planning and implementation stage.
- Noting the recent direct country approvals for the R21 malaria vaccine, the PPC member representing WHO explained that each country has the power to approve vaccines submitted to them. The Alliance, and in particular WHO, was working to accelerate the R21 malaria vaccine prequalification process, whilst also needing to rely on the vaccine manufacturer submitting evidence.
- One PPC member expressed concern about the decreased coverage rate for three doses of diphtheria-tetanus-pertussis (DTP3) and measles-containing vaccines. They mentioned their constituency concern of the risk of congenital rubella syndrome (CRS) and emphasised the need for clear vaccination guidelines. The Secretariat acknowledged the concerns and explained that countries can apply for measles rubella vaccines, and that the application process considers any related vaccine risks. Additionally, country coverage surveys are carefully reviewed to identify and assess potential risks.
- The PPC member representing the CSO constituency praised the progress in constituency engagement and suggested reporting be referenced in the first page of the Gavi Balance Scorecard. Additionally, they encouraged allocating roles for both global and local CSOs and ensuring funding reaches smaller CSOs. They also suggested benchmarking successful partners in this field.
- Expanding on the topic, another PPC member raised a concern about the need to include CSOs in the capacity building strategy, and encouraged the Secretariat to be aware of the dynamic in terms of community-based organisations that lack adequate funding, and those that were well-funded.

- The PPC thought the recommendations in the IRC report to be helpful, advised them to be implemented and agreed with the proposal to waive the need for an independent review for up to five low-risk and low-value country applications in 2023, noting that the Secretariat would follow PPC guidance and seek a similar waiver from the Governance Committee.

### **Decision One**

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

**Approve** a two-year extension to the US\$ 500 million in Equity Accelerator Funding (EAF) approved by the Board enabling countries to receive EAF disbursements until 2027, recognising that the COVID-19 pandemic has delayed design and implementation of EAF grants.

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## **5. Country Programmes Delivery Presentation**

- 5.1 The PPC Chair noted that this agenda item had been planned in response to requests from PPC members to learn more about the status of implementation of vaccination programmes in Gavi-eligible countries. She highlighted that the presentation had been prepared jointly by Gavi, UNICEF and WHO and that it would provide an Alliance view of the current situation.
- 5.2 Thabani Maphosa, Managing Director, Country Programmes Delivery, presented on the theme of planning and execution, focusing on matters such as the status of Equity Accelerator Funding applications, cash disbursement levels and timeliness, Accountability Frameworks, and support related to the Gavi Alliance Fragility, Emergencies and Displacement Policy, Zero-Dose approach, and Middle-Income Countries approach.
- 5.3 Ephrem Lemango, Associate Director of Immunization, UNICEF, presented on several key thematic areas, including on investments related to gender, demand, supply chain and Civil Society Organisation engagement.
- 5.4 Kate O'Brien, Director, Department of Immunization, Vaccines and Biologicals, World Health Organization, provided an overview on new vaccine introductions, with a focus on human papillomavirus (HPV), malaria, and measles vaccines.

### *Discussion*

- PPC members expressed appreciation for the joint presentation by partners that fully demonstrated the strength of the Alliance.
- On the guidance point that had been raised in the previous item on whether to temporarily revise the current risk appetite related to preventative measles campaigns given decreased population immunity and an increased number of



measles outbreaks, PPC members generally endorsed the approach proposed and commented on the ongoing need for timeliness and quality of campaigns. It was noted that there is a scheduled item on PPC workplan to review the Gavi Risk and Assurance Report in October 2023. The Chair suggested that the PPC should have a further discussion on measles during the following year, with a focus on exploring the use of campaigns, risk appetite, the evidence base and potential investment options.

- PPC members asked for more information about how the gender policy is being monitored and implemented and requested a deep dive session on gender. The Secretariat clarified that there will be a discussion about the annual review of the implementation of the gender policy at the PPC meeting in October 2023.
- One PPC member asked for more information about the one-dose regimen for HPV vaccine and whether countries were being encouraged to implement this schedule. It was clarified that it was the decision of countries whether to take up the one-dose schedule, which is currently still off-label, and that the WHO is providing guidance to the in-country coordination bodies (NITAGs).

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## 6. Hexavalent Investment Case

- 6.1 Aurélia Nguyen, Chief Programme Strategy Officer and Kate O'Brien, Director, Department of Immunization, Vaccines and Biologicals, WHO provided some introductory remarks (Doc 06).
- 6.2 Prof O'Brien outlined the pathway and key decisions and confirmed that all five support conditions, required to be met under the in-principle decision taken by the Board in 2018, had been fulfilled. She outlined the programmatic considerations, noted the polio eradication strategy is partially on track, and explained the value of the Hexavalent investment.
- 6.3 Ms Nguyen explained that switching to Hexavalent would come with initial additional costs for countries. She noted the co-financing costs to countries and saved costs to both Gavi and countries. She also outlined the risks, both in terms of approving a funding window and delaying a decision and emphasised the role of the Secretariat and partners to support and guide countries as they navigate this area.

### *Discussion*

- PPC members strongly supported the proposed recommendation, recognising the value and positive impact of the proposed Hexavalent programme. One PPC member described the programme as an excellent example of the Secretariat's market shaping abilities. As the programme gains traction, it is

expected to reveal additional benefits such as fewer injections and ancillary cost savings.

- The PPC underscored the importance of country-demand as being at the centre of the programme.
- When launching the programme, the PPC encouraged the Secretariat to leverage its partners and engage all sectors, including CSOs, technical experts and health workers.
- The PPC suggested it would be useful to evaluate the potential effects on both co-financing and ancillary costs, as well as the benefits, such as fewer injections and climate change impacts. The Secretariat acknowledged that countries planning to switch to the programme would require clear information on co-financing and assured the PPC that eligible countries would still receive co-financing exemptions in line with previous Board decisions. The Secretariat also recognised the impact of the programme switch on co-financing, and emphasised the importance of further review and discussions to find the best course of action for each country.
- One PPC member noted that some programme challenges may not as yet have been fully addressed and suggested providing additional information around the steps needed for a successful programme, as well as country feedback on programme demand and co-financing needs.
- One PPC member emphasised the importance of monitoring the country programme switch so as to avoid any potential disruption to programmes such as IPV and pentavalent. The Secretariat commented that it had identified areas where it could assist countries wishing to switch to the programme, and emphasised the importance of raising country awareness.
- Another PPC member described the vaccine industry's experiences and challenges as it relates to Hexavalent. These included difficulties to launch the vaccine, the prequalification process, and the delays caused by the COVID-19 pandemic. Additionally, they highlighted the need to ensure affordability. All these factors had played a significant role in the Hexavalent journey, and it was important to raise awareness about the obstacles.
- When asked about Hexavalent production through the African vaccine initiative, the Secretariat explained there are currently several manufacturers developing the vaccines and that African manufacturers would be part of the development discussions.
- The PPC noted potential communication challenges and encouraged the Secretariat to create a strong strategy to address questions directly, particularly in relation to any potential vaccine side-effects where clear communication is essential to overcome barriers to population acceptance.

- The PPC member representing the CSO constituency emphasised the importance of addressing vaccine confidence as particularly crucial since the programme could be viewed as a completely new vaccine initiative. The Secretariat acknowledged these concerns and affirmed its understanding and awareness of the impact of COVID-19 on vaccine confidence.
- In relation to inquiries around financial budget availability, the Secretariat confirmed there is currently adequate financial budget for the base case scenario. In the event of a high demand ratio, the Secretariat would seek Audit and Finance Committee (AFC) review.

### **Decision Two**

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

- a) **Approve** the opening of a funding window for Hexavalent vaccine for the administration of diphtheria, tetanus, whole-cell pertussis, hepatitis B, Haemophilus influenza b (Hib), and IPV antigens;
- b) **Note** that the initial estimates of the financial implications associated with the above approval for 2023-2025 are expected to be up to US\$ 62 million, and the US\$ 29 million estimated costs associated with base demand has been taken into account in the financial forecast to be presented to the Board in June 2023;
- c) **Note** that the initial estimates of the financial implications associated with the above approval for 2023-2025 for additional operational cost support and Secretariat and partner resources will be accounted for in the financial forecast to be presented to the Board in December 2023, following consultations with partners and countries;
- d) **Note** that the initial estimates of the financial implications associated with the above approval for the strategic period 2026-2030 are expected to be up to US\$ 430 million and contingent on financial resources being made available for the next strategic period; and
- e) **Note** that the initial estimates of the financial implications for both time periods are based on a fully loaded vaccine price and include saved ancillary costs and a one-time switch grant.

*Lamia Badarous (IFPMA) and Sai Prasad (DCVMN) recused themselves and did not vote on Decision Two above.*

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## **7. COVAX Update and Gavi's Role in a Future COVID-19 Vaccine Programme**

7.1 Richard Mihigo, Director, COVID-19 Vaccine Delivery, Coordination and Integration, introduced this item (Doc 07) and presented the proposed

progression from COVAX in 2022-2023 to a COVID-19 programme for 2024-2025.

- 7.2 Derrick Sim, Managing Director, Vaccine Markets and Health Security reviewed the key features of the programme which had been proposed to the Board in December 2022 and received an in-principle approval. He also provided an overview of the key assumptions that had been updated since the Board approval, including confirmation of the Strategic Advisory Group of Experts (SAGE) priority populations, revised demand projections, delivery strategy, and the resulting updated financial envelope.

### *Discussion*

- PPC members acknowledged the ongoing uncertainty related to the trajectory of the pandemic as well as demand for vaccines, and generally supported moving ahead with the proposed programme. The Secretariat noted that having an approved programme would allow the Alliance to respond in this uncertain period and that it would continue to follow the technical guidance of SAGE on appropriate use of vaccines. It was clarified the COVID-19 vaccine is proposed to be included in the Vaccine Investment Strategy 2024 process for any potential support beyond 2025.
- Several PPC members asked for further information about complementarity of resources with the various internal funding streams and with external sources. It was clarified that Gavi is working with Alliance partners and countries to have a clear picture of their vaccine and resource needs from Gavi, to complement their access to vaccines and resources from other sources, such as AVAT (the African Vaccine Acquisition Trust). The Alliance is also engaged with the African Union (AU) on integrating COVID-19 vaccine programmes into primary health care, and the AU had been closely engaged in the recent stock-take meeting in early May 2023.
- One PPC member highlighted the need to be responsive to country requests for technical assistance for integration of COVID-19 vaccination delivery. The Secretariat noted that its close engagement with countries was critical for understanding country demand and eventual needs for technical assistance.
- In relation to a question about expectations for how much of the CDS funds would flow through government systems, it was clarified that currently about 35% have been flowing through national systems, with the remainder through UNICEF, WHO and expanded partners, and that there would be a conscious effort to push as much of the CDS funding as possible to the government systems.
- One PPC member also encouraged the Secretariat to be more explicit in its materials about what 'local partners' means for this proposed programme and whether it includes CSOs.

- Several PPC members requested more transparency on the use of the AMC Investors Group to discuss matters related to the Pandemic Vaccine Pool funding and planned use of funds moving forward. It was clarified that the AMC Investors Group, which is comprised of a wider set of donors than those at the Gavi Board, had been convened to explore comfort levels among donors around several scenarios for use of their funds. It was also emphasised that these matters will ultimately come to the Board for decision.
- The PPC had a robust discussion on whether to recommend a further modification to the extent of procurement support that had been approved by the Board in December 2022 to remove any differentiation in support based on country income level, on the basis that the context had shifted since the Board approval, but ultimately the PPC agreed to proceed with the original proposed recommendation language.
- The PPC was unable to reach consensus on the recommendation below and the minority position expressed by Naomi Dumbrell on behalf of the United States/Australia/Korea (Republic of) donor constituency cluster will be reported to the Board.

### **Decision Three**

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

- a) **Approve** US\$ 711 million from the COVAX AMC for a new programme for COVID-19 vaccination in 2024-2025 contingent on:
  - a. Continuation of the WHO base-case scenario for the pandemic evolution requiring continued focus on high priority groups as per SAGE recommendation; and
  - b. Sufficient funding as confirmed by the Board in June 2023
- b) **Approve** the following country scope and extent of support for a 2024-2025 COVID-19 vaccine programme:
  - a. Country scope: AMC91 (Gavi54 and AMC37)
  - b. Extent of support:
    - i. Gavi54: Eligible for full vaccine procurement support without co-financing obligations and eligible for delivery support through existing CDS resources
    - ii. AMC37: Eligible for vaccine catalytic financing in line with the MICs Approach for vaccine procurement and eligible for delivery support through existing CDS resources

The Gavi Alliance Programme and Policy Committee:

- a) **Noted** that Gavi will cease to administer the COVAX Facility beyond 31 December 2023, with the COVAX Facility ending in accordance with its terms on or prior to such date.
- b) **Noted** that despite Gavi no longer administering the COVAX Facility beyond 31 December 2023, provision of COVID-19 vaccines would continue through Gavi per the proposed 2024-2025 COVID-19 vaccine programme, pending Board approval.
- c) **Noted** that the Alliance would provide guidance on COVID-19 programmatic integration and considerations for transition to the 2024-2025 COVID-19 vaccine programme, pending Board approval, as outlined in Part I, paragraph 2; and
- d) **Noted** that delivery funding for the 2024-2025 COVID-19 vaccine programme will be through a no-cost extension of COVID-19 Delivery Support.

*Lamia Badarous (IFPMA) and Sai Prasad recused themselves and did not vote on Decision Three above. Kate O'Brien (WHO), Ephrem Lemango (UNICEF), and Anne-Marie Mbengue Seye (CSOs) recused themselves and did not vote on Decision Three, point b) b) above.*

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## **8. Vaccine Investment Strategy 2018**

- 8.1 Marta Tufet Bayona, Head, Policy presented this item (Doc 08). She provided contextual remarks on the pausing of the Vaccine Investment Strategy (VIS) 2018 vaccines.
- 8.2 Dr Tufet outlined that following the PPC's request for further analysis, the Secretariat proposed a sequenced unpausing of the VIS 2018 vaccines, rather than a reassessment as part of VIS 2024. She explained the methodology considerations and potential trade-offs.
- 8.3 In terms of level of ambition, the PPC was being asked to provide guidance which would help steer the programme design.

### *Discussion*

- The PPC was supportive of unpausing all the vaccines paused under VIS 2018 and commended the Secretariat on its efforts in bringing the paper to the PPC.
- The PPC discussed whether or not the unpaused vaccines should follow a particular sequence. The PPC suggested that the Secretariat should provide

countries with the ability to choose themselves and thus avoid sequencing of vaccines where possible. However, should it be necessary to sequence the vaccine implementation, the PPC expressed its preference that the Hepatitis B (HepB) birth dose vaccine be prioritised.

- The PPC encouraged the Secretariat to make use of existing guidelines and programme planning. Noting the complexities and length of time to implement the rabies vaccine, for example, the PPC encouraged the Secretariat to continue information gathering on country demand and vaccine availability planning.
- Noting the preference for a menu of vaccines, the Secretariat outlined the complications and varying challenges of bringing the vaccines forward, noting the level of work and coordination, particularly as countries expect clear guidance and support from the Secretariat and Alliance Partners. The Secretariat also emphasised the importance of balancing idealistic goals with practical considerations to ensure success.
- The Secretariat pointed out that accelerating introduction timelines would also require commitment from Alliance partners, drawing lessons from programmes such as HPV and malaria, as well as either dedicating resources, or reallocating resources away from those programmes awaiting vaccine delivery.
- The PPC member representing UNICEF underlined the importance of partner-provided technical assistance, particularly in light of learnings from programmes, such as malaria, where health worker engagement had elicited good results. In this regard, the PPC also encouraged the Secretariat to consider broader partner opportunities, technical assistance expertise and utilise helpful processes to accelerate implementation.
- In relation to a question on the interlinkage between Hexavalent and DTP, the Secretariat explained that this linkage has been accounted for and that there was potential to revise down costs to align with the proposed decisions the Hexavalent Investment (Doc 06).
- In terms of level of ambition, the PPC acknowledged the importance for countries to maintain focus and continue prioritising routine immunisation, therefore it would be necessary for the Secretariat to exercise a lower level of ambition with lower programme implementation expectations, and with a higher level of risk tolerance.
- The PPC felt that a lower level of ambition would: i) create the most value at this point, ii) eventually be scalable and facilitate potential new vaccine touch points, iii) utilise expertise to inform on the related advantages of each vaccine; iv) encourage partner collaboration to address country demand; and iv) ensure ambition is aligned to country demand.

- The Chair noted the strong support for expediting the VIS 2018 programme implementation. She noted that while some countries had successfully completed their HPV rollout, they had not as yet received the malaria vaccine and that there could be a window of current capacity to implement the unpaused vaccines in response to country demand.

## **9. Vaccine Investment Strategy 2024: Longlist and Evaluation Frameworks**

- 9.1 Marta Tufet, Head, Policy, provided some introductory remarks on the Vaccine Investment Strategy (VIS) 2024 (Doc 09).
- 9.2 Dr Tufet summarised the historical view of Gavi's vaccine portfolio and explained how the VIS informs Gavi 6.0's strategy and investment through an evidence-based approach.
- 9.3 She outlined the analytical process and the decisions paths and explained that the PPC was being asked to consider a recommendation in relation to the first step of the process, namely which vaccines should be evaluated and how. She provided details on the eight pathogens in the proposed VIS 2024 longlist and the understanding of the full value of vaccines.
- 9.4 Finally, she gave an overview of the proposed vaccine delivery platforms and outlined the next steps towards a shortlist of pathogens.

### *Discussion*

- The PPC supported the recommendation and thanked the Secretariat for the consultative and inclusive approach in bringing the longlist of pathogens and evaluation criteria for its consideration.
- The PPC representative to the VIS Steering Committee gave a brief summary of the recent Steering Committee discussions which had centered around platform approaches and risk assessment. On the longlist of pathogens, it had discussed the evaluation criteria, the importance of deaths averted, the approach to life course vaccines, and other influencing factors, such as climate change.
- The PPC expressed its support for the evaluation criteria and emphasised the importance of transparency and to not lose sight that demand be country-driven, and information based. The PPC also encouraged the Secretariat to prioritise and bring focus to the feasibility criteria.
- Several PPC members mentioned the importance of evidence data to inform pathogen choice, whilst still maintaining Gavi 5.1 ambitions and focus on strengthening routine immunisation.



- One PPC member suggested that the Secretariat be mindful about expressing interest in a broad vaccine agenda before evaluating the progress of current initiatives, such as the malaria programme.
- The PPC noted the vaccine longlist extending beyond infants and children and suggested this could pose challenges in terms of complexity and costs. The PPC explained that there would need to be adequate investment to ensure success, whilst also being mindful not to divert resources from routine immunisation efforts.
- The PPC recognised the importance of the health worker platform in delivering vaccines to key population groups and providing a vital role in promoting immunisation and providing information, thus making it crucial to strengthen this platform.
- The PPC also requested that the work on platforms considers other platforms as a comparator (e.g. adolescent health, 9 months, infant) and that this work tie back with Gavi's HSIS work. The CEO outlined the Secretariat's reflections on delivery platforms and exploring new approaches, particularly as the health system focus shifts to ageing populations and indices move from lives saved to health system cost savings.
- In relation to evaluation criteria, one PPC member encouraged early signalling for manufacturer investment, continued manufacturer consultations and discussions, and proposals for long-term market shaping, all of which is crucial for vaccine investment and timely production.
- The PPC member representing UNICEF explained the EPI programme, currently focused on support for pregnancy and childhood vaccines, and suggested this could potentially expand to cover life course vaccines. The Secretariat acknowledged that a broader approach is welcomed, as well as accelerated Vaccine Innovation Prioritisation Strategy (VIPS) support and innovation.
- The PPC highlighted the need for further discussion around aligning VIS 2018 and VIS 2024 processes. The PPC thought that the analysis conducted under VIS 2018 was well-balanced and a similar structure was suggested for VIS 2024. The Secretariat explained it was exploring VIS approaches with clearer criteria on platform design and methodology that would consider each vaccine's impact on health models, disease-specific analysis, and additional support.
- On the VIS Steering Committee, the Secretariat clarified that a working group is tasked with providing information on health worker and antenatal platforms, which would inform the VIS 2024 strategy.

- The Secretariat outlined the next steps where, after further analysis, the Secretariat would report back to the PPC on the shortlist of vaccines and seek feedback and support on the proposed approach. Should the Secretariat find support, further work would be done which would feed into the Gavi 6.0 strategy.

#### **Decision Four**

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

- Approve** the longlist of pathogens (hepatitis E, m-pox, dengue, COVID-19, tuberculosis, group B streptococcus, chikungunya, and shigella) with licensed or pipeline products, to assess as new potential investments in vaccines and immunisation products through the VIS (Vaccine Investment Strategy) process;
- Approve** the evaluation criteria for potential new investments in vaccines and other immunisation products primarily intended for ***endemic disease prevention***; these include key ranking criteria (health impact, value for money, equity and social protection, Gavi's comparative advantage and economic impact) and modulating criteria that inform the ranking (global health security impact, other impact, broader health system benefits, implementation feasibility, alternative interventions, and contribution to global agenda);
- Note** the evaluation approach for potential new investments in vaccines and other immunisation products primarily intended for ***epidemic disease prevention***; centred around four key questions: i) disease burden and risk, ii) vaccine impact and feasibility, iii) fit for Gavi and partners, and iv) financial implications; and
- Request** as part of the VIS, the Secretariat undertake further analyses to evaluate the potential value of providing support to develop, strengthen and deliver vaccines at new touchpoints for specific target populations (e.g. health workers and pregnant people), building upon lessons learned from other Gavi programmes.

*Lamia Badarous (IFPMA) and Sai Prasad (DCVMN) recused themselves and did not vote on Decision Four above.*

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### **10. Gavi's role in Pandemic Prevention, Preparedness and Response**

- 10.1 Seth Berkley, CEO, introduced this topic and emphasised that the Alliance has long been a contributor to pandemic prevention, preparedness and response as part of its core work, including through routine immunisation, campaigns for prevention, investing in strengthening health systems, investment in pandemic, epidemic and outbreak responses through the global vaccine stockpiles, and using learnings from COVID-19 over the last three years. He highlighted that

the global virtual pooled inventory (GVPI) concept that is outlined in the paper as well as Gavi's proposed role stemmed from discussions with Alliance partners and the Coalition for Epidemic Preparedness Innovations (CEPI) about how to fill a key gap in product development to accelerate product licensure and enable faster access.

- 10.2 He reminded the PPC of the role that Gavi played in the response to the 2014-2015 Ebola Zaire outbreak with its forward-looking Advance Purchase Commitment that made investigational doses available before there was a licensed vaccine. He noted that the GVPI concept builds on that experience and aims to replicate elements of that process.
- 10.3 Derrick Sim, Managing Director, Vaccine Markets and Health Security provided additional context on the discussions to date on Gavi's proposed role in PPPR and reviewed the key features of the GVPI concept (Doc 10).
- 10.4 David Kinder, Director, Development Finance, reviewed and provided an update on the four targeted PPPR areas that the Gavi Board had approved in December 2022 as part of its discussions on Gavi 5.1, namely: i) retaining and enhancing required capabilities for the next pandemic; ii) financial innovation; iii) resilient routine immunisation (RI) programmes; and 4) diversification of regional manufacturing.

#### *Discussion*

- PPC members commended the Secretariat on how far this workstream has advanced since the last PPC meeting.
- With respect to the proposed GVPI, PPC members recognised there was a gap in product development. The PPC requested the Secretariat return to the PPC, and subsequently the Board, in the next cycle with a proposal that more clearly sets out roles and responsibilities, plans for alignment and coordination, mechanisms to identify antigens, and that avoids duplication of efforts. However, in order to ensure that Gavi would be equipped to proceed if called upon by partners to support a GVPI before the next PPC meeting, the PPC agreed to recommend a time-limited envelope for this purpose until December 2023. It was clarified that the Secretariat planned to return to the PPC at its next meeting in October 2023 with a more developed plan.
- On the potential Advanced Market Commitment to support new manufacturers in Africa, PPC members welcomed the opportunity to provide guidance and suggested including additional touch points on design elements as work continues in this key area. PPC members flagged that it will be important to consider: i) the potential premium that would come with such a mechanism and whether such an elevated cost would be acceptable for market health and for how long that would remain true; ii) the eligibility criteria, with options that would avoid non-regional actors from taking undue advantage of this mechanism, and options explicitly open to global manufacturers both discussed; iii) the potential

need for some form of solidarity mechanism to promote and add certainty to regional demand; and iv) other key risk mitigation modalities that need to be taken into account.

- With respect to the innovative pandemic health financing, or potential ‘Day-Zero Pandemic Financing Facility’, PPC members advised that Gavi should take lessons from recent experience that early no-regret funding for procurement was critical. PPC members also cautioned that there are many financing options being developed and discussed, and it will be important to consider the development of this mechanism in the context of the wider ecosystem and avoid the creation of silos.

**Decision Five**

Noting that the Secretariat plans to return to the PPC in October 2023 and the Gavi Board in December 2023 with a fully scoped proposal for Gavi in GVPI, which would include, inter alia, confirmation of the role of Gavi and other partners and a financial assessment with a suggested cost envelope, the Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it:

**Approve** a time limited envelope until the December 2023 Board meeting of up to US\$ 10 million, for GVPIs for Ebola Sudan and Marburg vaccines if there is a need and an explicit ask from WHO and/or CEPI to Gavi. Any individual agreements with manufacturers would require Phase II data for Ebola Sudan or Marburg candidate vaccines to be available. The individual agreements would be subject to review and approval of Gavi’s Market-Sensitive Decisions Committee. This decision would not set a precedent for future Gavi investments.

*Lamia Badarous (IFPMA) and Sai Prasad recused themselves and did not vote on Decision Five above.*

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**11. Review of Decisions**

- 11.1 Joanne Goetz, Head, Governance, reviewed the decision language with the Committee which was approved by them.

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**12. Any other business**

- 12.1 The Chair warmly thanked Seth Berkley for his leadership during PPC meetings during his tenure as CEO.
- 12.2 After determining there was no further business, the meeting was brought to a close.

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Mrs Joanne Goetz  
Secretary to the Meeting

## Attachment A

### Participants

#### Committee Members

- Anne Schuchat, Chair
- Awa Marie Coll Seck
- Adrien de Chaisemartin
- Michael Kent Ranson
- Ephrem Lemango
- Kate O'Brien
- Abdelkadre Mahamat Hassane
- Eduardo Humberto Retes
- Alexandra Rudolph-Seeman
- Karin Westerberg
- Naomi Dumbrell\*
- Lamia Badarous
- Sai Prasad\* (Agenda Items 1, 2, 4, 6, 7, 9-12)
- Anne Marie Mbengue Seye
- Saad Omer (Day One)
- Seth Berkley, Chief Executive Officer
- Hanna Nohynek

#### Regrets

- Beth Arthy
- Roli Singh

#### Other Board members attending

- Takeshi Akahori\* (Day One)
- Francesca Manno\* (Agenda Items 5-12)

#### Other guests

- Lourenço Villa-Loboos, Nestor Advisors
- Daniel Genberg, Nestor Advisors

#### Observers

- Ruzan Gyurjyan, Special Advisor to the EURO Constituency
- Muluken Desta, Special Advisor to the Anglo-Africa Constituency
- Annick Sidibé, Special Advisor to the Francophone-Lusophone Africa Constituency
- Rolando Pinel, Special Advisor to the PAHO Constituency
- Phonethipsavanh Nouanthong\*, Special Advisor to the WPRO Constituency
- Pratap Sahoo, Special Advisor to the SEARO Constituency
- Zaeem Ul Haq, Special Advisor to the EMRO Constituency
- Stella Villares, Special Adviser, Gavi Board Chair

#### Gavi Secretariat

- David Marlow
- Jalaa' Abdelwahab (Agenda Items 4, 5 and 6)\*
- Nadine Abu-Sway (Agenda Items 2 and 3)
- Johannes Ahrendts
- Hannah Burris
- Assietou Diouf (Day One)
- Hope Johnson
- David Kinder (Agenda Item 10)
- Joanne Goetz
- Brenda Killen
- Ian MacTavish (Day Two)
- Thabani Maphosa (Day One)
- Richard Mihigo (Agenda Items 5 and 7)
- Meegan Murray-Lopez (Agenda Items 1, 5, 7 and 10)
- Aurélia Nguyen
- Tanya Robinson (Agenda Items 4, 6, 8 and 9)
- Marie-Ange Saraka-Yao
- Colette Selman (Day Two)
- Derrick Sim (Agenda Items 7 and 10)
- Marta Tufet (Agenda Items 2-4, 7-9)

\*Attending virtually