

Gavi Alliance Programme and Policy Committee Meeting 24-26 October 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 14.00 Geneva time on 24 October 2023. Anne Schuchat, Programme and Policy Committee (PPC) Chair, chaired the meeting.
- 1.2 The Chair welcomed all participants, in particular new members, including Hannah Haaij (Industrialised Governments - Netherlands); Mohamed Jama (Implementing Countries - Somalia); Pavani Ram (Industrialised Governments - United States); and Rob Whitby (Industrialised Governments - United Kingdom).
- 1.3 The Chair also welcomed David Marlow, CEO (Interim) who was attending the meeting for the first time in his new capacity.
- 1.4 As the PPC Charter allows for any Board or Alternate Board Members to observe Committee meetings, the Chair welcomed the participation of Francesca Manno (Alternate Board Member, Italy) who would be joining for parts of the meeting.
- 1.5 The Chair provided an update on the Board and Board Committee evaluation process. At its last meeting, the Governance Committee appointed a Subcommittee to oversee implementation of the recommendations related to Board and Committee functioning and effectiveness. One specific area which related to the PPC recommended a need for strengthened linkages between the PPC and the Independent Review Committee, which moving forward will present at each PPC, and the Evaluation Advisory Committee.
- 1.6 In this regard, the Chair 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 October 2023 and would continue to serve in a liaison role between the EAC and PPC.
- 1.7 The Chair highlighted the establishment of the Alliance Partnerships & Performance Team (AAPT) and noted that two PPC members, Abdelkadre Mahamat Hassan (Implementing Governments - Chad) and Pavani Ram (Industrialised Governments - US), are members of the APPT.
- 1.8 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).

- 1.9 The minutes of the PPC meetings of 16-17 May 2023 were tabled to the Committee for information (Doc 01b). The minutes had been circulated and approved by no objection on 3 August 2023.
- 1.10 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.
- 1.11 The Chair noted comments from the Civil Society Organisation (CSO) constituency using BoardEffect, as well as additional comments shared by email by the Bill & Melinda Gates Foundation. She encouraged other committee members to provide viewpoints using BoardEffect before PPC meetings.
- 1.12 She invited Kent Ranson to provide key updates from the October 2023 EAC meeting. He highlighted several areas where feedback was requested from the PPC, including on: i) the Evaluation and Learning Report 2022-23 (Doc 04 - Appendix 1); ii) the draft report for the Mid-term Evaluation; and iii) the role of evaluations in Gavi 6.0 (noting that planning for evaluations in Gavi 6.0 will begin shortly and a review of the evaluation function is scheduled for 2024). He informed the PPC that the EAC had provided guidance that a proposed Middle-Income Country (MIC) Evaluation be postponed until mid-2024 and recommended a desk-review be undertaken. Finally, highlighting the importance of the communication between the Board, EAC and PPC he stated that the EAC Chair had been invited to attend the Board Retreat in December.

2. CEO Update

- 2.1 David Marlow, CEO (Interim), provided an update on several key areas including: the emphasis on Gavi's three core priorities; the importance of an external focus and stakeholder collaboration; progress on Gavi 6.0 strategy development; and an integrated Senior Leadership Team (SLT) under the One Gavi approach. He also noted two key thematic areas for the meeting were performance and risks, and priorities and investments.
- 2.2 Mr Marlow highlighted the impact of the external environment and global context on Gavi's work and its strategy development. He particularly noted externalities such as fragility and conflict, climate emergency, a deteriorating macro-economic outlook, a renewed focus on Universal Health Coverage (UHC) and Primary Healthcare (PHC), reshaping of global health architecture and Pandemic, Prevention and Preparedness Response (PPPR), country voices, and health innovations.
- 2.3 He provided an overview of Gavi 5.1 priorities for the last quarter of 2023 and discussed must-wins and operational excellence enablers. He highlighted key strategic enablers such as the EVOLVE project, COVAX integration, and

strengthened Alliance partnerships. He also emphasised the progress made so far as detailed in the Annual Progress Report 2022.

- 2.4 Mr Marlow discussed performance as illustrated in the Balanced Scorecard and emphasised the focus on making progress in areas including reducing zero-dose children and increasing DTP3 coverage. Additionally, he addressed concerns that have been raised through recent surveys and stressed his commitment to improving the culture at Gavi.
- 2.5 Mr Marlow also reported on recent high-level missions, including to Nigeria in which Gavi and the Government of Nigeria successfully aligned on priorities and focus areas. He highlighted the high-level HPV launch taking place in Nigeria on 24 October. He reiterated the importance of implementing country voices and informed the PPC about the Memorandum of Understanding (MoU) that had recently been signed with the African Union.
- 2.6 He emphasised the importance of the Alliance and provided examples of positive collaboration with partners including the Global Fund to Fight AIDS, Tuberculosis and Malaria, as well as well as the potential for positive impact through the APPT.
- 2.7 Concluding the CEO update, Mr Marlow noted the substantial amount of pre-reading and information that is provided to the PPC and the potential of streamlining this for future meetings.

Discussion

- The PPC thanked Mr Marlow and commended him on the progress and his commitment towards amplifying country voices and driving operational excellence.
- The PPC welcomed the opportunity to comment on the size of the meeting pack provided to the committee and encouraged the Secretariat to explore whether the necessary information could be presented in a more concise manner. Some PPC members also noted that the agenda could dedicate more time to Gavi core work as covered in the Strategy, Programmes and Partnerships (SPP) agenda item and programme update, noting that a significant share of the PPC is focused on new approaches and tools (PPPR, Vaccine Investment Strategy (VIS), African Vaccine Manufacturing Accelerator (AVMA)). In reference to comments on the Board and Board Committee Evaluation and whether the EAC had a role in this, he clarified that this evaluation did not fall under the purview of the EAC and that the recommendations would be considered by the Governance Committee on behalf of the Board.
- The Secretariat responded to a question on the implications of the Future of Global Health Initiatives (FGHI) for Gavi and noted the multi-stakeholder effort underway to agree on next steps and short-term wins.

3. Read-Out from Audit & Finance Committee Meeting

- 3.1 In the absence of Assietou Diouf, Chief Financial Officer, David Marlow, CEO (Interim), provided an update on the AFC meeting which had taken place on 17 October 2023. He stressed the focus on transparency between PPC and AFC discussions, through sharing of information, improved management reporting and leveraging the Balanced Scorecard for a holistic and systematic review of performance.
- 3.2 He summarised the AFC's endorsement of key items including the Risk and Assurance Report, risk elements of the Ethics, Risks and Compliance Charter and the 2024 Audit & Investigation Plan. He noted that the AFC was supportive of amendments to the Risk Appetite Statement with minor clarifying adjustments.
- 3.3 He stated that the AFC had endorsed the financial forecast and mentioned that there was limited financial flexibility for any new significant priorities. He also flagged the importance of the discussion on in-country cash balances.
- 3.4 Mr Marlow reported that the AFC noted the Operational Excellence agenda is continuing at pace and requested a deeper dive at upcoming meetings on the EVOLVE project as well as the IT landscape.
- 3.5 Finally, he gave an overview of the key programmatic drivers of the updated financial forecast including anticipated impact in Gavi 5.1 and Gavi 6.0 and key observations.

Discussion

- The PPC thanked Mr Marlow for this update and the transparency it provided with respect to Committee deliberations.
- Some PPC members flagged that new programmes – including malaria and MMCV - will have major impact on Gavi's financials, and that the programmes should be operationalised in a way that maximises value for money. The Secretariat indicated that this would be taken into account and that it would revert with updates through regular Governance processes.
- Mr Marlow emphasised the importance of the EVOLVE project that is working to improve grant-making process, making it more agile and country focused.
- In reference to comments on the upcoming replenishment cycle and the need for discussion on the drivers of Gavi 6.0 cost and trade-offs, Secretariat colleagues noted this request, and reviewed the 5-year replenishment cycle, including the AFC's discussion on replenishment at this stage as part of the regular planning cycle.

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

- 4.1 Aurélia Nguyen, Chief Programme Officer, introduced this item and explained that the purpose of the item was to provide a broad view in terms of progress on the Gavi 5.1 strategy, programmes, and partnerships, as well as Gavi's must-wins (Doc 04). She reviewed the Balanced Scorecard and progress against Strategic Goal One, including an overview of several recent cases of outbreaks.
- 4.2 Johannes Ahrendts, Director, Strategy, Funding and Performance presented an update on zero-dose and underimmunised children, and outlined three options for investment in *The Big Catch Up* to enable countries to reach children who were missed during the pandemic due to pandemic-related backsliding.
- 4.3 Dr Ahrendts also provided an update on transitioning countries and backsliding, as well as the no-cost extensions requested by Papua New Guinea and Timor-Leste to reduce the risk of backsliding.
- 4.4 He reported on progress related to the pilot for the opt-in model of the Independent Review Committee (IRC) reviews for grant applications of very low-risk and low value as well as the request for an expanded pilot.
- 4.5 Maria Thestrup, General Counsel (Interim) & Chief Ethics, Risk and Compliance Officer, commented on the updated Risk Appetite Statement that was presented to the PPC, which proposes to reduce the risk appetite level for vaccine-preventable disease (VPD) outbreaks from balanced to low and reflects the ongoing need for timeliness and quality of campaigns.

Discussion

- The PPC was supportive of an aggressive response to reaching zero-dose children missed during the pandemic and wished to encourage countries to be as ambitious as possible in drawing up plans to reach them. In this regard, PPC members encouraged the Secretariat to proceed with an emergency lens, recognising that the opportunity to reach the missed age cohort is time-limited and to apply flexibility, with the understanding that some countries will be able to go further than others in identifying zero-dose children and should go as far as they can.
- The PPC requested that the Secretariat remove any conditionalities from the proposed recommendation language that might discourage countries from preparing ambitious plans. In this regard, the PPC also asked that the Secretariat revise Doc 04 Annex F for the Board and make clear that considerations related to co-financing, assessment of external resource streams, and shipment of doses should be implemented flexibly as part in operationalising the Big Catch-Up to appropriately manage these risks.

- PPC members also acknowledged the risk of creating perverse incentives in terms of programme design and target setting for *The Big Catch Up* as well as the risk of increased wastage and re-vaccination and requested that this be captured in the revised Annex. PPC members noted that it was expected these risks could be adequately managed through routine planning efforts.
- In relation to a question on accountability and how to monitor results for the Big Catch Up, it was clarified that there will be a Monitoring, Evaluation and Learning (MEL) plan established that would rely on surveys, but also on government systems.
- PPC members also recognised the tremendous progress made through human papillomavirus (HPV) revitalisation efforts.
- Several PPC members requested further information about malaria following the update provided in this agenda item, including with regards to the linkages with the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Secretariat indicated it would look for opportunities for further discussion.
- PPC members were supportive of the requests for no-cost extensions for Papua New Guinea and Timor-Leste. Several PPC members noted that it would be important to consider eligibility, as well as ways to minimise ad-hoc requests such as these, within the context of Gavi 6.0.
- With respect to the IRC pilot, PPC members queried the level of ambition and whether the Secretariat has the capacity to implement this approach. The Secretariat clarified that the proposal is trying to be reasonable but ambitious, and that selecting 20 applications would imply 20-30% of all IRC applications expected in Q1-2 2024. The Secretariat noted that it plans to bring an update of the IRC Terms of Reference to the Board for decision in the first half of 2024.
- PPC members were supportive of the updated Risk Appetite Statement and praised the quality of the Risk and Assurance Report. PPC members commented that: i) it would be useful for partners to be able to feed into the iteration of risks; ii) Secretariat capacity should be considered high risk and partner capacity should also appear in the list of risks; iii) sustainability should potentially remain a high risk; and iv) it is important to preserve the intent that fragile settings should be prioritised.

Decision One

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

- a) **Approve** flexibility for the Secretariat to provide fully funded catch-up doses for children missed during the pandemic for an initial amount of US\$ 290 million subject to countries developing robust plans and taking into account the risk

mitigation measures as laid out in Annex F to Doc 04 as amended by discussions at the PPC;

- b) **Note** that the above approval reflects the urgent need for ambitious catch-up efforts for the period 2024-2025 and is contingent on available funding from the COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) as confirmed by the Gavi Audit and Finance Committee;
- c) **Approve** that Papua New Guinea be exceptionally granted a no-cost extension of the US\$ 60 million 2019 Strategy funding envelope from December 2025 to December 2027, thereby extending the country's accelerated transition period to December 2027;
- d) **Request** an external review of the Papua New Guinea strategy be conducted by December 2026; and
- e) **Approve** that Timor-Leste be exceptionally granted a no-cost extension of its post-transition support December 2023 to December 2025.

5. Gavi's Role in Pandemic Prevention, Preparedness and Response

5a Pandemic Prevention, Preparedness and Response Approach

- 5a.1 Derrick Sim, Managing Director, Vaccine Markets and Health Security/Office of the COVAX Facility, presented an update on the Alliance's approach to pandemic prevention, preparedness and response (PPPR) and outlined three proposed investments aligned with that approach for the remainder of Gavi 5.1 (Doc 05a).
- 5a.2 He noted that these investments were being presented in response to the Board's request in June 2023 for the Secretariat to present options for the use of remaining COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) funding that consider current grant agreements and possibilities for reprogramming, relate to preparing and responding to COVID-19 and future health emergencies, and were developed in full consideration of enhanced collaboration with other pandemic recovery and pandemic prevention, preparedness, and response initiatives.
- 5a.3 Dr Sim also noted that there were additional options detailed in the paper that had been presented to the AMC Investors Group for consideration, but ultimately had not been put forward for PVP funding due to restrictions on the use of many donors' funds, and that these options would be considered for the Gavi 6.0 strategic period.
- 5a.4 Ngashi Ngongo, Chief of Staff and Head of Executive Office, Africa Centres for Disease Control (Africa CDC), attending as a guest and at the invitation of the

Chair, indicated his enthusiasm to work closely with Gavi on PPPR initiatives following a recent joint workshop in Geneva and given alignment between Gavi's approach and Africa CDC goals. With respect to the proposed health worker immunisation platform, Dr Ngongo also reported on their interest in this area with a new project between Africa CDC and the Mastercard Foundation that plans to protect four million health workers on the African continent.

Discussion

- PPC members appreciated the 'ready countries, ready vaccines, ready coalition' framework as outlined in the paper and considered this a good approach to PPPR moving forward.
- PPC members were supportive of a coalition of vaccine partners for PPPR that is resourced, equipped with the right capabilities and capacities, and prepared with a clear plan to respond on Day Zero in an upcoming pandemic, and potentially in certain outbreaks and epidemics, as some members noted a continuum from outbreaks, epidemics and pandemics.
- Some PPC members expressed concern about setting up a duplicative or parallel process and raised questions of how the coalition would fit with other ongoing processes (e.g. the interim medical countermeasures network (I-MCM-Net) and the Intergovernmental Negotiating Body (INB)). The Secretariat clarified that it is intended that the coalition would work through existing partnerships and mechanisms, including through the working group XVAX, WHO R&D Blueprint, the Medical Countermeasures Delivery Platform, and others. In this regard, PPC members requested that the recommendation language be explicit that coordination would be through existing mechanisms.
- PPC members requested further detail on the expected participation in the coalition and within which organisation the roles will be placed, and the need for inclusion across existing and new partners, including from CSOs, and with broad geographic spread. The Secretariat confirmed that broad participation is envisaged and the coalition would be codesigned with partners.
- The PPC also provided guidance on a Day Zero Financing Facility for Pandemics, which would fund critical activities via innovative finance tools and specifically to create a pool of First Response standby funding that could be deployed from Day Zero of the next pandemic. PPC members recognised that at-risk and contingent financing are both critical for timely and equitable pandemic response.
- PPC members advised that it would be important to be more specific with respect to the details of the mechanism, including on governance arrangements, potential programmatic uses of the funding, the exact triggers for the funding and whether multi-country outbreaks or epidemics might be

included, and modalities to avoid funds sitting unused for indeterminate periods of time.

- In relation to the proposal to establish a health worker immunisation platform to deliver key vaccines and strengthen health worker vaccination programmes, complementary systems and capacities, the PPC was not prepared to make a recommendation to the Board at this time. While some PPC members found value in the approach, the overall conclusion was that this be considered as part of Gavi 6.0 deliberations along with the proposed health worker touchpoint (Doc 07).
- For this proposal, PPC members asked for more detail on the antigen selection, country selection, cost of the pilot programme, and noted the need to work with a broad set of new technical groups, including occupational health and safety bodies.
- The PPC also took note of three other PPPR activities that had been presented to the COVAX AMC Investors Group. Despite general interest from the AMC Investors Group for these proposals, legal constraints on the use of the COVAX AMC PVP funds prevented the Secretariat from putting these options forward to the PPC. These three included: i) expanded outbreak detection, prevention, and response; ii) advance purchase commitment for Measles-Rubella Microarray Patches (MR-MAPs) and capabilities for future outbreak response; and iii) Global Virtual Pooled Inventories (GVPIs). These proposals can be considered alongside other future potential investments for Gavi's 6.0 PPPR approach as part of Gavi 6.0 strategy development. Noting that these proposals were presented only for information at this time, some PPC members expressed support for them and encouraged further consideration, particularly of MR-MAPs, for Gavi 6.0.

Decision Two

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

- a) **Approve** up to US\$ 22 million to support a coalition of vaccine partners outlined in Annex A to Doc 05a as amended by discussions at the Programme and Policy Committee (PPC) to be committed during the Gavi 5.1 strategic period, in line with Gavi's approach to pandemic preparedness, prevention, and response (PPPR);
- b) **Note** that the investment would be to vaccine partners, coordinating through existing mechanisms, ensuring that the scope of activities covers critical linkages across outbreaks, epidemics, pandemics, and resilient routine immunisation programmes and continues to align with the Intergovernmental Negotiating Body (INB) and medical countermeasures (MCM) network deliberations;
- c) **Note** the PPCs guidance on the programmatic aspects of the investment proposals outlined in Annex A to Doc 05a for the Day Zero Financing Facility for Pandemics

for which an estimated amount of up to US\$ 500 million could be allocated, noting that the Gavi Audit and Finance Committee would recommend the Day Zero Financing Facility for Pandemics to the Board for approval;

- d) **Note** that this approval and any additional approvals are contingent on available funding from the COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) as confirmed by the Gavi Audit and Finance Committee;
- e) **Note** that any additional approvals required in the further development of these proposals will be brought back to the Board through the relevant Board Committees as per standard Gavi governance process and in line with Gavi policy;
- f) **Note** that the investment proposals were developed with full consideration of enhanced collaboration with other pandemic recovery and PPPR initiatives and considered by the COVAX AMC Investors Group, as requested by the Board in June 2023, and were supported as options for the use of COVAX AMC PVP funds; and
- g) **Note** that the PPPR approach will be further refined for Gavi 6.0, and associated investments considered as part of Gavi 6.0 strategy development, including but not limited to investments presented to the AMC Investors Group that did not receive funding.

Kate O'Brien (WHO), Ephrem Lemango (UNICEF), and Anne-Marie Mbengue Seye (CSOs) recused themselves and did not vote on Decision Two, point a) above.

5b African Vaccine Manufacturing Accelerator (AVMA)

- 5b.1 Marie-Ange Saraka Yao, Chief Resource Mobilisation and Growth Officer, introduced and presented the main features of the proposal for an African Vaccine Manufacturing Accelerator, including the plan for designing the governance elements of the instrument (Doc 05b).
- 5b.2 Derrick Sim, Managing Director, Vaccine Markets and Health Security/Office of the COVAX Facility, explained how this proposal fits within the wider ecosystem and architecture, noting that AVMA is just one of four pillars of Gavi's regional manufacturing strategy and that this is closely aligned with the African Union's vision.
- 5b.3 Ngashi Ngongo, Chief of Staff and Head of Executive Office, Africa Centres for Disease Control (Africa CDC), recognised that if approved, this instrument would be a gamechanger in terms of efforts to scale up local manufacturing on the African continent and commended Gavi for being the lead international organisation in terms of putting together a concrete proposal for support to this agenda. Dr Ngongo also noted that from his perspective, it will be important to remain pragmatic and realistic that there is no instrument that is perfect from

the start, and this will need iteration. Finally, he reported that the Africa CDC is committed to advocate with the political leadership on the continent to fully align and support the AVMA and has already started working with other African Union (AU) bodies on a legal instrument in this respect.

Discussion

- PPC members recognised the extensive consultations that had been undertaken since the last discussion on this topic.
- PPC members also took note of the statement that had been provided to the PPC by the African Vaccine Manufacturing Initiative (AVMI) prior to the meeting.
- The PPC was supportive of the AVMA concept and noted the critical role that Gavi should play given its strength in financial innovation and market shaping for vaccines. PPC members wished to send a strong signal to industry and investors that the Gavi Alliance was prepared to proceed with the establishment of the mechanism by recommending the headline terms of AVMA to the Board.
- PPC members requested that further analysis be carried out in relation to four elements that had been included in the term sheet provided as Annex A to Doc 05b and that further detail be provided in a revised version to the Board in December 2023, including with respect to: i) an expanded list of priority antigens (potentially including Gavi's 'category B' antigens with improved target product profiles); ii) increasing the Fill & Finish-only incentives; iii) whether vaccines manufactured through Contract Manufacturing Organisation (CMO) arrangements were eligible for AVMA support; and iv) confirmation of the pandemic platforms that were detailed in the paper (mRNA and viral vector).
- PPC members noted there is still significant work to do over the coming six months to operationalise AVMA and finalise the implementation of the mechanism.
- PPC members acknowledged the risks related to the establishment of AVMA and requested that the Secretariat undertake further analysis of legal, regulatory, and market risks and their implications. The Secretariat was also asked to develop comprehensive mitigation plans and potential options to pivot the mechanism if adverse consequences emerged.
- PPC members also discussed the importance of work to build the supportive African vaccine manufacturing ecosystem including on issues such as regulatory approval; workforce and tech transfer support; and ensuring regional demand for regionally manufactured vaccines. All these issues will need to be addressed but are broader than the AVMA mechanism. It was flagged that different parts of the Alliance (such as WHO on regulatory approval) and other partners would need to be called upon to support work on these challenges. It

was also noted that there are existing frameworks that could be built on and enhanced related to capacity building and regulatory strengthening activities, and that one of the other purposes of AVMA was to act as an incentive for these broader conversations to happen.

- PPC members also recognised that demand materialisation for vaccines manufactured on the African continent will be a key factor for success and expressed appreciation that the Africa CDC and AU are tackling this work.

Decision Three

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

- a) **Approve** the establishment of the African Vaccine Manufacturing Accelerator (AVMA) as an instrument to provide time-limited financial support to accelerate the expansion of commercially viable vaccine manufacturing in Africa, in accordance with the base design criteria set out in Annex A to Doc 05b as amended in follow up to discussions at the PPC;
- b) **Note** that this approval is contingent on available funding from the COVAX Advance Market Commitment (AMC) Pandemic Vaccine Pool (PVP) as confirmed by the Gavi Audit and Finance Committee. Under the base proposal, a capitalisation of up to US\$ 1 billion is required;
- c) **Note** that the investment proposals were developed with full consideration of enhanced collaboration with other pandemic recovery and PPPR initiatives and considered by the COVAX AMC Investors Group, as requested by the Board in June 2023, and were supported as options for the use of COVAX AMC PVP funds; and
- d) **Request** that the Secretariat brings back to the Board the following in the first half of 2024: further analysis of legal and regulatory risks relating to the provision of Gavi's support; the articulation of intermediate milestones and review points; the establishment of a Treasury function; proposed governance arrangements with related legal terms and conditions established; and a high-level mapping of key dependencies related to regional demand, regulatory strengthening and prequalification functions at WHO.

Lamia Badarous (IFPMA) and Sai Prasad (DCVMN) recused themselves and did not vote on Decision Three, point a) above.

6. Multivalent Meningococcal Conjugate Vaccine Programme

- 6.1 Aurélia Nguyen, Chief Programme Officer, presented a proposed expansion of the meningococcal programme to include support for multivalent

meningococcal conjugate vaccines (MMCV) containing at least serogroups *Neisseria Meningitidis* (Nm) A, C and W (Doc 06).

- 6.2 She noted that new policy recommendations had been issued by WHO's Strategic Group of Experts on Immunization (SAGE) and that a product aligned with the assumptions in the 2018 Vaccine Investment Strategy investment case had been pre-qualified in July 2023. On this basis, she reported that the conditionalities from the November 2018 Board decision on MMCV as part of the VIS 2018 had been deemed to be met.

Discussion

- PPC members were supportive of the proposal. They noted that many public health experts, including some members of the PPC, had dedicated decades to fighting meningitis and were enthusiastic to see further strengthening of tools to combat it.
- PPC members noted that while this is an expensive programme, it is the right thing to do. Rather than broadly rolling out MMCV, several members of the PPC, encouraged the Secretariat to target the vaccine in geographies with demonstrated evidence of non-A serotype. It was also recommended that the Secretariat take into consideration the cost-effective use of MMCV in the vaccine programme design and roll-out. The Secretariat confirmed that work on diagnostics was underway to get the right diagnostics to help the programming, such as subnational targeting.
- One PPC member asked about whether flexibility could be applied to the list of high-risk countries based on epidemiologic considerations, given the deep interest from countries. The Secretariat confirmed flexibility will be needed, particularly given the uncertainty of the data available.
- In response to a question about the stockpile for outbreak response, which is managed by the International Coordinating Group, it was clarified that the plan is to use the multivalent vaccine for this purpose moving forward in order to have the benefit of a single tool available for deployment regardless of the serogroup causing the outbreak.
- One PPC member queried whether the costing for the programme included integrated approaches. It was clarified that this was not part of the costing but would be encouraged where possible. In this regard, an example was provided of Nigeria where integrated measles, yellow fever, and meningitis A campaigns had been conducted, and the same approach could be applied for the multivalent vaccine.
- In relation to a question about market health and whether tenders would be limited to pentavalent vaccine or could contain just three strains, it was clarified that while the plan was to retain flexibility and encourage the entrance of

vaccines that did not necessarily contain all five strains, it was not expected that any non-pentavalent vaccines would meet the assumptions in the short term.

- PPC members agreed that this item could be placed on the consent agenda for the December 2023 Board meeting.

Decision Four

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

- a) **Approve** expanding the meningococcal programme to include support for multivalent meningococcal conjugate vaccines (MMCV) containing at least serogroups *Neisseria Meningitidis* (Nm) A, C and W aligned with the proposed vaccination strategy and including additional investments as outlined in Annex A to Doc 06;
- b) **Note** that the initial estimates for financial implications associated with the above approval for the period 2023-2025 are US\$ 136 million and for the period 2026-2030 are US\$ 326 million to US\$ 577 million, the latter contingent on financial resources being made available for the next strategic period;
- c) **Note** that initial estimates are based on a fully loaded vaccine price for MMCV and include associated cash grant costs, while estimates for the period 2023-2025 also include additional costs for technical assistance and Secretariat expenses. Potential changes in the underlying assumptions of these estimates will be reflected in future financial forecasts; and
- d) **Approve** the provision of campaign operational cost support up to US\$ 0.65 per dose to repurpose meningococcal vaccines with short shelf-life part of the meningococcal stockpile, aligned with the amended International Coordinating Group (ICG) Standard Operating Procedure (SOP).

Lamia Badarous (IFPMA), Sai Prasad (DCVMN), Kate O'Brien (WHO), and Ephrem Lemango (UNICEF) recused themselves and did not vote on Decision Four above.

7. Vaccine Investment Strategy 2024: Proposed Shortlist

- 7.1 Kelechi Ohiri, Chief Strategy, Policy and Innovation Officer, introduced this item and described the process and timeline for the Vaccine Investment Strategy 2024 (Doc 07).

- 7.2 Marta Tufet Bayona, Head, Policy, reviewed the vaccines under consideration in the VIS 2024, detailed the analyses that had been conducted, and presented the shortlist.
- 7.3 She also noted that as part of the process, there had been consideration of the value in taking a more horizontal health systems approach to vaccine introduction, and evaluate potential support to develop health worker and maternal/newborn touchpoints to reach these priority populations with vaccines more efficiently and effectively. This work had been overseen by the VIS Steering Committee, as well as by an ad hoc working group, which had included additional members outside of the vaccinology sector.
- 7.4 Helen Rees, Chair of the VIS Steering Committee, attending as a guest and at the invitation of the Chair, commented on the rigour, independence, and quality of research and documentation of the process. She noted the complexity of the assessment, particularly with respect to changing epidemiology, and mentioned dengue and its recent outbreaks as an example. She also reflected on the deliberations related to proposed additional touchpoints, and noted these are not straightforward but could move Gavi more in line with the broader Immunization Agenda (IA) 2030 vision.

Discussion

- The PPC thanked the VIS Steering Committee, ad hoc working group, and the Secretariat for the meticulous and impressive work that has been done.
- PPC members asked for clarification about several technical elements of the analysis, including with respect to dengue and why the estimated health impact was not visible when compared to the other antigens. It was clarified that this is due to the ranking methodology and that it should be interpreted as having the lowest health impact compared to the other vaccines evaluated (tuberculosis, group B streptococcus and shigella). It was also noted that burden of disease data was severely limited in Gavi-eligible countries and that other factors such as recent outbreaks and potential impact of climate change on its epidemiology had led to it being upgraded.
- PPC members also queried why maternal influenza had not been included in the short list. It was explained that historically there was low demand for this vaccine, and there remained uncertainty of its potential health impact. It was also noted that Maternal Influenza vaccine had been deprioritised in the VIS 2018 process.
- On mpox, one PPC member asked about what the learning agenda might entail. The Secretariat indicated that it could look at uptake, feasibility, acceptability and epidemiology of the disease in Africa. It was also clarified that vaccines against epidemic diseases could be evaluated outside the 5-year VIS cycle in response to a public health threat or a research and development

milestone, meaning that mpox could potentially be brought back to the PPC in that context if needed.

- In relation to COVID-19, PPC members asked whether it was being treated differently within the VIS 2024. It was clarified there were reasons to consider this as a special case compared to the other shortlisted antigens, given that there is an existing Gavi vaccine programme. The PPC wished to specifically mention in the recommendation language that the intention is to develop investment options for a time-limited COVID-19 programme.
- With respect to the proposed evaluation of touchpoints for health worker and maternal/newborn vaccination, the PPC considered that the health systems strategy process that is already underway will consider Gavi investments in these and potentially newer touchpoints, so did not feel it necessary to include recommendation language at this time ahead of the Gavi 6.0 deliberations.

Decision Five

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

For vaccines for endemic disease prevention:

- a) **Request** the Secretariat to develop possible investment options for further consideration for tuberculosis, group B streptococcus, shigella and dengue vaccines;

For vaccines for epidemic-prone diseases:

- b) **Request** the Secretariat to develop possible investment options for further consideration for hepatitis E vaccines;
- c) **Request** the Secretariat to monitor and update living assessments for Chikungunya and Mpox vaccines, including potential investments in learning agendas in consultation with WHO and other partners; and

For COVID-19 from 2026:

- d) **Request** the Secretariat to develop possible investment options for further consideration of a continued time-limited COVID-19 vaccine programme from 2026.

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

8. COVAX Update

- 8.1 Derrick Sim, Managing Director, Vaccine Markets, Health Security/Office of the COVAX Facility, provided an update on key achievements of COVAX after nearly three and a half years since COVAX had been created with partners (Doc 08).
- 8.2 He also provided an update on the integration and closure of COVAX taking place across people, processes and technology dimensions, and touched on how COVAX learnings are being incorporated moving forward.
- 8.3 Richard Mihigo, Director, COVID-19 Vaccine Delivery, Coordination and Integration presented an update on COVID-19 vaccine delivery to date as well as on the approved COVID-19 programme for 2024-2025, which is on track in terms of implementation of the design as well as operationalisation.

Discussion

- The PPC commended the Secretariat and Alliance partners who worked shoulder to shoulder in this endeavour.
- PPC members asked about the use of COVID-19 Delivery Support (CDS) contingency funds to date. The Secretariat clarified that it appears most countries now have the resources they need to support their delivery ambitions and noted that it was built into the CDS3 application process that some of these resources should be committed to support broad integration activities.
- One PPC member commented on communications at country level and lessons learned from the COVID-19 pandemic in terms of use of social media. It was clarified that there have been examples of innovative approaches that countries have starting to experiment with using both traditional means of communicating the benefit of immunisation, but also taking advantage of social media using young people, for example in collaboration with Africa CDC, using their Bingwa Initiative with the young people.
- One PPC member asked about whether ancillary costs had been reduced in line with vaccine demand. The Secretariat indicated that more detail would be available through reporting on the whole programme; however, costs that had not been utilised would be put into the PVP.
- In relation to a question about the safeguards in place to minimise wastage, the Secretariat noted its continued efforts together with countries and partners to be vigilant around demand and forecasting from an operations perspective. It was clarified that to date, Gavi understands that above country wastage across countries is about 5%, while COVAX is lower at 3%. Given the emergency context, rapidly evolving situation with unpredictability in demand and lag times in supply, this rate is considered acceptable.

- Several PPC members commented about the importance of applying learnings for the future and how partners can continue to work together to pre-empt and be aware of the complexities in any public health emergency. The Secretariat acknowledged the importance of resilient health systems and taking a broad approach to prevention and preparedness part of the PPPR, and to continue to work with a broad set of partners in order to continue to advance this work.

9. Report of the Independent Review Committee (IRC)

- 9.1 Rose Leke, Chair of the Independent Review Committee (IRC) presented on several areas including: the increasing number and value of applications received; an improved focus on equity and gender-responsiveness within the applications; improved epidemiological analysis in applications related to malaria and measles/measles-rubella; and finally, the implementation of recommendations from the IRC evaluation.
- 9.2 Aleksandra Caric, Independent Review Committee member, also provided comments during the discussion portion of the item.

Discussion

- The PPC congratulated Dr Leke on winning the 2023 Virchow Prize for Global Health for her exceptional lifetime achievements in strengthening global health, pioneering infectious disease research towards a malaria-free world, and relentless dedication in advancing gender equality.
- The PPC commended the valuable work of the IRC and recommended regular engagement between the Board, IRC and PPC.
- Several PPC members asked whether applications received by the IRC were meeting the 10% CSO requirement. The presenters stated this was not always met and noted the challenges of identifying and engaging appropriate CSOs at global, regional, and local levels.
- PPC members queried the impact on countries of multiple financing windows across agencies, who can often feel overburdened by funding applications. The presenters noted ongoing collaboration between the IRC, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other key partners to align on processes.
- In relation to measles applications, one PPC member commented on the importance of having funding available specifically for technical assistance and a roster of technical assistance partners that can be mobilised quickly.

- PPC members discussed the lack of prominence of applications relating to reaching zero-dose children. The presenters acknowledged the complexities of categorisation of zero-dose within countries and stated that more work needed to be done to optimise the reach of campaigns.
- One PPC member queried how the IRC follows up on projects once funding has been approved and dispersed. The presenters acknowledged that it was critical to obtain robust data post-campaign to enable such analysis including the effectiveness of implementation and campaigns.
- The presenters noted that the Secretariat conducts thorough initial pre-screening of applications and that the IRC was working on processes for expediting some applications.

10. Country Programmes Delivery Presentation

- 10.1 Thabani Maphosa, Managing Director, Country Programmes Delivery, introduced this agenda item and noted that it was complementary to the Strategy Programmes and Partnerships: Progress, Risks and Challenges discussion on day one (Agenda Item 4). He presented on priorities and programme performance including focus areas for the Alliance; progress towards 2025 targets; select achievements from Gavi's targeted focus on country capacity; movement of cash balances as of December 2023; progress on CSO engagement and associated challenges; progress made with operationalising COVID-19, Zero-Dose Immunisation Programme (ZIP); the Fragility, Emergencies and Displaced Populations Policy (FED); and progress on transition road maps by countries in accelerated transition.
- 10.2 Ephrem Lemango, Associate Director of Immunization, UNICEF, presented on several key thematic areas related to programme deep dives including action to reduce stockouts at all levels; progress towards achieving adequate, well-managed and maintained cold chain capacity as well as systems and associated challenges; and Gavi's continued focus and investments to strengthen capacity in countries to improve demand for immunisation and Primary Health Care (PHC).
- 10.3 Kate O'Brien, Director, Department of Immunization, Vaccines and Biologicals, World Health Organization, provided an overview on new vaccine introductions, with a focus on malaria, and human papillomavirus (HPV) revitalisation vaccines. Additionally, she provided updates on the zero-dose approach and *The Big-Catch Up* initiatives, Vaccine Investment Strategy (VIS) 2018, and other new programmes. She also discussed the impact of pandemic-related backsliding and evolving outbreaks of Vaccine Preventable Diseases (VPD).

Discussion

- The PPC expressed appreciation for the joint presentation that fully demonstrated the strength of the Alliance.
- Several PPC members discussed the engagement of the Secretariat with CSOs and asked for clarity on the selection process and role of CSOs as implementation partners. The Secretariat agreed that it is important to have a data-informed understanding of the CSO landscape, in addition to examining learnings from previous relationships. They clarified the remit of Gavi's new funding mechanism for CSOs that is intended to increase the quantity, diversity, and quality of CSO engagement. It was noted that this funding mechanism will be fully managed by the Secretariat.
- PPC members highlighted the desire for increased transparency between the Secretariat and implementing countries in addition to the wish to move towards country-led coordination and ownership. In the same vein, it was noted that countries are being overburdened and require continuous support, particularly in planning and implementation.
- In reference to a question on the challenges Nigeria is experiencing in meeting its roadmap to 2028 targets, the Secretariat explained that Nigeria like many other countries was affected by externalities such as the global pandemic which has impacted other areas of progress.
- Several PPC members noted the importance of good quality data to strengthen and inform several initiatives, including visibility into vaccine and supply chain data as well as its use by health workers and decision makers within countries which is critical to achieving zero-dose targets. The presenters noted that there is a coalition working on data in fragile settings, and a deep-dive session could be organised if there was sufficient interest.
- On maintaining and managing decommissioning of cold chain units, the presenters noted that expertise had been developed within countries and guidelines for repurposing and decommissioning the units had been published. It was also noted that 60% of the cold chain procured by Gavi through CCEOP is solar powered.
- One PPC member asked for more insight into vaccine hesitancy. The presenters highlighted the multi-layered aspects of this, including accessibility and proximity of services, in addition to gender and cultural factors. It was emphasised that overall, vaccine uptake was greater than vaccine hesitancy.
- On discussions around immunity, backsliding and recent outbreaks, the presenters noted that there are significant immunity gaps and outbreaks such as diphtheria were not identified sooner largely due to lack of robust systems including capacity and knowledge to enable recognition of the symptoms.

11. Update on Middle-Income Countries Approach

11.1 Adriana Jimenez Cuen, Director, Middle Income Countries (MICs) provided an update on Gavi's MICs Approach, including: an overview of progress; mitigating backsliding in former-Gavi countries; vaccine introduction in former and never-Gavi countries; and lastly, challenges, lessons learnt and considerations for the future (Doc 11).

Discussion

- The PPC commended the Secretariat for the considerable progress made over the last six months and noted the importance of the MICs Approach for Gavi 6.0.
- The Secretariat highlighted that early data indicates positive responses to the MICs approach and that countries are being incentivised to introduce new vaccines with limited support from Gavi. Acknowledging this, several PPC members highlighted the importance of this progress taking into account potential future vaccines that will be highly relevant in these countries. One PPC member noted technical and implementation assistance was necessary for some regions such as the Americas.
- The Secretariat emphasised the role of the Alliance and regional partners in operationalising the approach including an expanded set of partners such as CSOs, the private sector and educational institutions.
- Several PPC members emphasised the importance of a tailored and flexible approach when assessing and responding to country readiness for new vaccine introductions, given the non-linear dimension to country progression. One PPC member advised the Secretariat consider health system gaps and provide sufficient flexibilities in technical support.
- As discussed by the Evaluation Advisory Committee (EAC) in October, the PPC highlighted the importance of a data-informed desk review and noted that this may be followed by an evaluation in mid-2024.
- Similarly, some PPC members stressed the importance of data for informing resource allocation and illustrating impact for Gavi 6.0. It was suggested that the Secretariat considers using country case studies including detail on the specific objectives against which funding has been committed.
- Several PPC members asked for information about the status of the MICs Financing Facility and how it is supporting the objectives. One PPC member highlighted how this mechanism facilitated predictability and country commitment, and allowed manufacturers to have better visibility.
- The importance of supporting fragile countries who are not able to support coverage was also noted.

12. Update on Implementation of the Gavi Gender Policy

- 12.1 Alex de Jonquières, Director, Health Systems & Immunisation Strengthening introduced this item and discussed three priorities to accelerate implementation, including providing technical assistance at country level, increasing understanding and skills, and investing in measurements (Doc 12).
- 12.2 He asked the PPC for feedback on the proposed approach specifically in relation to the proposed implementation measures.

Discussion

- The PPC commended the frankness of the Secretariat in discussing challenges in overcoming gender barriers to immunisation, increasing participation of women and girls in health programme decision-making, and addressing coverage gaps between boys and girls where they exist.
- The PPC encouraged continued separation of the work being done by the Secretariat on the Gender Policy and the Prevention of Sexual Exploitation, Assault and Harassment (PSEAH).
- PPC members supported the focus on gender-specific technical assistance to provide high quality gender analysis, in addition to examining best practice from Alliance partners and other actors within the public health landscape. Furthermore, the Secretariat was encouraged to co-design solutions with women and girls in implementing countries.
- Emphasising the role of CSOs in tackling misinformation and providing advocacy support, PPC members encouraged the Secretariat to engage CSOs as key implementation partners. In relation to capacity building, one PPC member suggested targeting government staff as advocates.
- PPC members noted the importance of well-validated indicators that can be reported on by countries and encouraged post-implementation data gathering included sex-disaggregated data. Close alignment with the Secretariat's Monitoring, Evaluation and Learning (MEL) team was also suggested.
- Whilst commending the allocation of dedicated funds to support the gender learning agenda, PPC members encouraged the inclusion of this within centralised zero-dose and Gavi 5.1 learning efforts.
- One PPC member requested that a future update to the PPC include more information on how the Secretariat was set up to deliver on the Gavi Gender Policy.

13. Review of Decisions

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

14. Any other business

- 14.1 The Chair warmly thanked outgoing PPC members Alexandra Rudolph-Seemann (Governments - Industrialised), Lamia Badarous (Vaccine Industry - Industrialised) and Sai Prasad (Vaccine Industry - Developing) for their contributions to the PPC and noted the continued engagement of Alexandra and Sai with the Board.
- 14.2 After determining there was no further business, the meeting was brought to a close.

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 (Agenda Items 5b-14)
- Eduardo Humberto Retes (Agenda Items 4-14)
- Mohamed Jama
- Alexandra Rudolph-Seeman
- Hannah Haajj
- Rob Whitby
- Pavani Ram
- Lamia Badarous
- Sai Prasad* (Agenda Items 5a-8, 11-12)
- Anne Marie Mbengue Seye
- Saad Omer*
- David Marlow, Chief Executive Officer (Interim)
- Hanna Nohynek

Regrets

- P. Ashok Babu

Other Board members attending

- Francesca Manno*

Other guests

- James Hargreaves*(Agenda Items 1, 5a-5b (in part), 6-7, 9, 11-12)
- Ngashi Ngongo* (Agenda Items 5a-5b)
- Helen Rees* (Agenda Item 7)
- Rose Leke (Agenda Item 9)
- Aleksandra Caric (Agenda Item 9)

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 UI Haaq, Special Advisor to the EMRO Constituency
- Stella Villares, Special Adviser, Gavi Board Chair
- Mary Gallagher*, Special Adviser, CSO constituency
- Lauren Franzel-Sassanpour*, WHO (Agenda Items 1-4, 6-14)
- Benedict Millinchip*, WHO (Agenda Items 5a-5b)

Gavi Secretariat

- Aurélia Nguyen
- Marie-Ange Saraka-Yao
- Kelechi Ohiri
- Pascal Barollier
- Maria Thestrup (Agenda Item 4)
- Thabani Maphosa
- Derrick Sim (Agenda Items 1-5, 7-9, 11)
- Brenda Killen
- Johannes Ahrendts
- Hope Johnson
- Hannah Burris
- David Kinder (Agenda Items 5a-5b)
- Richard Mihigo (Agenda Items 8 and 10)
- Adriana Jimenez Cuen (Agenda Items 10-11)
- Alex de Jonquières (Agenda Items 4, 5a, 7, 9-10, 12)
- Marta Tufet (Agenda Items 4-5a, 7-8)
- Joanne Goetz
- Lindsey Cole (Agenda Item 9)
- Aviya Khan (Agenda Items 1-3, 9-12)
- Meegan Murray-Lopez (Agenda Items 4-5a/b, 6-8)

*Attending virtually