

Gavi Alliance Programme and Policy Committee Meeting 15-16 May 2024

Hotel la Barcarolle, Prangins, 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 15 May 2024. Anne Schuchat, Programme and Policy Committee (PPC) Chair, chaired the meeting.
- 1.2 The Chair welcomed all participants, in particular new members, including Lakshmi Somatunga (Implementing Countries - Sri Lanka); Hitoshi Murakama (Industrialised Governments - Japan); Julie Hamra (Vaccine Industry - Industrialised); Rajinder Suri (Vaccine Industry - Developing); and Ngashi Ngonzo (Research & Technical Health Institutes).
- 1.3 The Chair welcomed Cécile Billaux (European Commission), who was a PPC member-elect at the time of the meeting. The Chair noted that given that the appointment to the PPC was already with the Board for approval, she had agreed exceptionally that Ms Billaux could attend the meeting and contribute fully in the discussions.
- 1.4 The Chair also welcomed Gavi's new CEO, Sania Nishtar.
- 1.5 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) and Alexandra Rudolph-Seemann (Alternate Board member, Germany) who would be joining virtually.
- 1.6 The Chair informed the PPC that James Hargreaves, Chair of the EAC, would be joining the meeting remotely for part of the meeting.
- 1.7 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack). The Chair noted for the record that she had been invited to join a Scientific Advisory Committee for a planning grant and phase IV trial of an Respiratory Syncytial Virus (RSV) vaccine in pregnancy and that this would be included in her declaration of interest going forward.
- 1.8 The minutes of the PPC meeting of 24-26 October 2023 were tabled to the Committee for information (Doc 01b). The minutes had been circulated and approved by no objection on 14 February 2024.
- 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 noted comments from the World Bank and Japan on the Board Effect discussion board. She informed the PPC that for the first time the meeting would benefit from French simultaneous interpretation, and she noted that the Secretariat had trialled a new paper template for this meeting and invited the PPC to provide their feedback.
- 1.11 The Chair invited Kent Ranson to provide key updates from the March 2024 EAC meeting. Dr Ranson highlighted ongoing centralised evaluations, including the Mid-Term, the Zero-Dose, and the COVAX evaluations. He highlighted future evaluations where PPC input would be welcome including on: i) the Middle-Income Country Strategy Evaluation; ii) the Big Catch-Up; and iii) the African Vaccine Manufacturing Accelerator (AVMA) Evaluation. He noted that a review of the Gavi evaluation function was currently underway to inform the Gavi 6.0 approach. He informed the PPC that an open question remains around how to best provide PPC input to the EAC's work and proposed a PPC-EAC half day joint meeting in the near future. Finally, he noted that should there be an interest from any Board member sitting on the PPC to join the EAC, that there would be an opportunity to do so.

2. CEO Update

- 2.1 Sania Nishtar, CEO, shared key reflections on her immediate priorities as incoming CEO, including the Gavi 6.0 strategy development and the replenishment workstream, underpinned by a listening and learning journey.
- 2.2 In reference to the Gavi 6.0 strategy, she highlighted her approach in working towards reconciliation of diverging vantage points and priorities that are represented across the different stakeholders on the Board. The PPC meeting represents an opportunity to continue discussing the design and operationalisation of the strategy in the lead up to the Board meeting in June 2024.
- 2.3 In relation to the Gavi replenishment, the CEO referred to an overall constrained fiscal environment where traditional donors have competing priorities and are under political pressures. Nevertheless, donors continue to extend resounding support to Gavi, but they do require efficiencies, optimisation across all spending envelopes and more granular reporting. The CEO will continue to engage at the international level to advocate for Gavi, including at the upcoming Group of Seven (G7) summit that will take place in Italy in June 2024, paving the way to the Investment Opportunity that will be launched in Paris and co-hosted by France and the African Union on 20 June 2024, alongside the launch of the African Vaccine Manufacturing Accelerator (AVMA).
- 2.4 Dr Nishtar underlined her appetite to shape country work. She noted that she had already visited the Central African Republic (CAR) and Nigeria, two countries with a high number of zero-dose and under immunised children, as

part of her commitment to countries and fragile contexts. She reiterated that countries should be at the centre of Gavi's work, and relayed countries request for donors to harmonise their requests which pose challenges to countries in responding to different reporting requirements. She also reported on meeting with a number of Alliance partners on the ground.

- 2.5 In reference to collaboration with other organisations, she noted that partnership with the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund) is of great interest, with huge potential to build synergies and collaboration particularly on malaria, where both organisations should have a coherent front facing approach.
- 2.6 Finally, Dr Nishtar referred to an active plan in engaging with Ministers of Health during the upcoming WHO World Health Assembly meeting.

Discussion

- The PPC extended a warm welcome to Dr Nishtar and expressed deep appreciation of her commitment to place countries at the top of her priorities.
- The PPC welcomed the emphasis on advancing the Lusaka Agenda, which needs to be integrated in Gavi's work.
- Partnership strengthening and advancing the collaboration agenda with the Global Fund, the Global Financing Facility (GFF) and with the Africa Centres for Disease Control and Prevention (CDC) was underscored, noting the need to remain cognisant of what Gavi can and cannot do. Efficiency of the Alliance will require focus on using areas of critical strength, leveraging all capable partners, and embedding critical shifts in the learning from COVID-19.
- With regards to the constrained fiscal space in countries and domestic pressures in donor countries, several PPC members underlined the need for maximising available resources through focused approaches and joint efforts.
- Several PPC members underlined that coordination on the ground remains challenging for countries, as well as for Civil Society Organisations (CSOs), which undermines country ownership.
- Several PPC members referred to the zero-dose agenda, noting that a standard approach cannot address this issue, with fragility being a critical determinant. The lack of infrastructure and human resources continue to be obstacles in reaching and immunising these children.
- Refreshing Gavi's operating model and the cumbersome grant making processes was highlighted by several PPC members.

- With regards to evaluations, the Secretariat was encouraged to share the outcomes and recommendation of the different evaluations.
- In responding to a query on challenges and opportunities, the CEO noted that as she took up her role she found a well-run and a well-governed organisation underpinned by a decentralised decision-making model. She noted opportunities to improve on the reporting side and deployment of new technologies. With regard to grant making and high transaction costs to staff and countries, she underscored the opportunity to mainstream change through the EVOLVE project, which is looking at efficiencies. Dr Nishtar highlighted challenges related to the environment where donor expectations can create obstacles to coordination and collaboration. Gavi will continue to try to create synergies, particularly on the malaria vaccine workstream, despite facing an ecosystem that disincentivises organisations to cooperate.

3. Read-Out from Audit & Finance Committee Meeting

- 3.1 David Marlow, Chief Operating Officer and (Acting) Chief Financial Officer, introduced this item and provided a summary of the key messages from the Audit and Finance Committee (AFC) meeting which had taken place on 7 May 2024.
- 3.2 Ian MacTavish, Director, Finance & Chief Accounting Officer, provided additional detail on the Financial Forecasts for Gavi 5.1, the COVAX Advance Market Commitment (AMC) and the COVID-19 programme, and reviewed the key programmatic drivers of the updated financial forecast including malaria, cholera and the Big Catch-up.

4. Update on Collaboration with Other Organisations

- 4.1 In the interest of time, the presentation relating to this item (Doc 04) was taken as read and Hope Johnson, Adviser to the CEO, Strategic Initiatives, and Richard Mihigo, Director, Programmatic and Strategic Engagement (Africa CDC and AU), responded to comments from the Committee.

Discussion

- The PPC welcomed the ambitious collaboration agenda and urged Gavi to move towards joint efforts with key partner organisations, underlining transparency, simplification and strategic partnerships for impact.
- The PPC expressed appreciation for the collaborative tone on the malaria workstreams, including for the Gavi-Global Fund joint Board technical briefing

on malaria which had taken place in April 2024. The need for clear communication plans to countries was highlighted as critical in this regard.

- The PPC underlined the importance of the Lusaka Agenda to ensure that countries are put at the forefront and stressed the need for progress on common metrics on health systems and tools, better domestic coordination and avoidance of fragmentation, as well as the necessity to have a road map to take this work forward.
- With regard to country engagement timelines, the Secretariat noted that it would focus on efficiency and impact. The Secretariat indicated it would map out information on where opportunities lie and would quickly move to approach countries that could be interested; however, the collaboration agenda is country driven and will depend on country choices, vision of success, and pace.
- The Secretariat was encouraged to be clear on the operational plans between each of the proposed workstreams to identify necessary policy changes and processes that need to evolve.
- Several PPC members enquired about the Terms of Reference (TOR) of the potential Joint Committee Working Group and called on the Secretariat to avoid creating parallel decision-making bodies. Some PPC members expressed interest in joining the Committee including the World Bank, UNICEF and WHO. The Secretariat clarified that the Joint Committee Working Group ToRs will be presented to the Governance Committee and Board in June 2024.
- The PPC welcomed the strengthened partnership with Africa CDC, given the importance of aligning activities across the Alliance with the broader partnership landscape and leveraging the capabilities of each partner. This stresses the need for transparency and clarity on the specifics of the discussions on programmatic engagement and ensuring complementarity through existing coordination mechanisms.
- With reference to funding activities with Africa CDC, the Secretariat clarified that a grant agreement is under consideration covering key activities aligned with Gavi 5.1 strategic objectives.
- Several PPC members underscored the importance of including polio eradication and collaboration with the Global Polio Eradication Initiative (GPEI) on transition under the proposed four workstreams.
- The CEO reiterated her commitment to lead the collaboration agenda together with the Executive Director of the Global Fund, noting that strong commitment underpinned by a partnership mindset would be vital to make progress on this agenda.

5. Update on EVOLVE Project

- 5.1 In the interest of time, the presentation relating to this item (Doc 05) was taken as read and Thabani Maphosa, Managing Director, Country Programmes Delivery, responded to comments from the Committee.

Discussion

- PPC members expressed strong support for the EVOLVE agenda and also supported the proposed strategic shifts in the target operating model.
- With respect to the Lusaka Agenda, PPC members encouraged the Secretariat in its shift from donor-centric to country-centric grant management, and to consider how the process would improve disbursement and lighten the mechanism for accessing funding in practice.
- PPC members recognised that the model's anticipated greater efficiency and effectiveness would outweigh the required trade-offs and potential change in risk appetite.
- Given that the project is behind on its initial workplan, it was noted that moving forward the project would be comprehensively reviewed, and adjustments would be made for the next phase of execution.
- PPC members supported the proposal to consolidate seven different cash grants into one cash envelope for Gavi 6.0 but expressed differing views on whether Partners' Engagement Framework (PEF) Targeted Country Assistance should be included in the consolidation. In this regard, one PPC member representing implementing countries requested that country empowerment and control be examined carefully as it relates to funding flows and that the Alliance take steps to improve on its approach.
- PPC members also asked about progress related to channelling funds through government systems and any further work on this planned for Gavi 6.0. The Secretariat clarified that although this workstream is outside of the EVOLVE project, there has been good progress, with the exception of two countries, Kenya and Bangladesh.
- PPC members referenced an upcoming meeting that would take place in Washington DC to discuss how partners engage with Gavi. It was noted that the meeting had been requested by expanded partners that had experienced difficulties with Gavi's procurement system and that the meeting would be hosted by Thabani Maphosa and David Marlow to explore a possible reset.

6. **Gavi 5.1 Strategy, Programmes and Partnerships: Progress, Risks and Challenges**

- 6.1 Aurélia Nguyen, Chief Programme Officer, provided an update on progress on Gavi 5.1 by reviewing results captured in the Balanced Scorecard and detailed progress on Strategic Goal 1, including on outbreaks, cholera, human papillomavirus (HPV) revitalisation, and malaria (Doc 06).
- 6.2 Johannes Ahrendts, Director, Strategy, Funding & Performance, reviewed progress on Strategic Goals 2, 3 and 4, including on operationalisation of the Big Catch-Up, co-financing, and vaccine market health.

Discussion

- PPC members commented on several strategic areas including the continued trend of increased number outbreaks under Strategic Goal 1. There were questions related to timeliness of response, and the Secretariat noted that there is work underway to look at how to best leverage the resources that are locally available, leveraging other sources of funds including Partners' Engagement Framework (PEF) funds and Health Systems and Immunisation Strengthening (HSIS) support.
- Linked to outbreak detection and response, the PPC discussed vaccine preventable disease surveillance, the link to diagnostics and how these fit together. The Secretariat clarified that this is an active area of work, which has expanded from yellow fever diagnostics to new vaccines like cholera. In addition, the Alliance Partnership and Performance Team (APPT) is reviewing progress in this area and will continue to engage on this important topic.
- On measles, where outbreaks are ongoing, PPC members noted it would be important to consider the way forward in Gavi 6.0 to ensure the approach is fit for purpose.
- In relation to the Big Catch-Up, it was noted that with the focus in-country on zero-dose children, there has been a strong push to take advantage of the opportunity to integrate bivalent oral polio vaccine (OPV). It was also noted on the Big-Catch Up that there were important in-country policy dimensions, with legislative considerations as well as supply implications, that would need to be carefully considered.
- Several PPC members commented on the highly complex roll-out of the malaria vaccine, including on the importance of addressing inaccurate rumours about vaccine effectiveness and building on lessons learned, and requested a further chance to discuss this topic.
- PPC members also discussed new introductions of human papillomavirus (HPV) and were pleased with the progress made towards the target of

immunising 86 million girls by 2025. The opportunity to switch to an off-label, single dose regimen, in line with the recent WHO Strategic Group of Experts on Immunization (SAGE) recommendation on this topic. It was noted that some countries are uncomfortable with off-label use and Gavi will need to communicate carefully about this, based on WHO guidance.

- One PPC member reflected on the significant progress in diversity of partners at local and global levels that has strengthened Gavi's ability to work in hard-to-reach areas and encouraged Gavi to draw lessons for Gavi 6.0 from the Civil Society and Community Engagement workstream.
- PPC members also raised the issue of supporting countries for vaccine prioritisation and the Secretariat noted this involves: i) ensuring Gavi countries have access to evidence and SAGE guidance; ii) providing tools, frameworks and dedicated support; and iii) supporting country capacity and systems via for example National Immunization Technical Advisory Groups (NITAGs) and other national stakeholders.
- With respect to comments on country capacity and the Leadership, Management and Coordination workstream, the Secretariat indicated that despite progress there are still significant capacity constraints and it is intended that the emphasis will shift to helping countries prioritise and optimise their vaccine portfolios.
- One PPC member queried whether on health systems strengthening (HSS), given current discussions on Gavi 6.0 funding levels, it would be worth already taking steps to smooth the spending curve and reduce amounts prior to Gavi 6.0. The Secretariat clarified that the forecast has already been reduced by US\$ 500 million by taking into account the focus on COVID-19 Delivery Support (CDS), and HSS and Equity Accelerator Funds (EAF) have already been adjusted.
- In response to a question about understanding the actual source of funds used to pay co-financing, the Secretariat clarified that it does have this view and while it has been variable year-on-year, in 2023 80% came from country budgets, with 19% from World Bank loans and 1% from other sources (e.g. UNICEF).

7. Joint Alliance Update on Country Programmes

- 7.1 In the interest of time, this update item was taken as read (Doc 07) and no comments were taken.

8. Report of the Independent Review Committee (IRC)

- 8.1 Rose Leke, Chair of the Independent Review Committee (IRC) presented this item (Doc 08) and was joined by the two IRC Vice Chairs, Bolanle Oyeledun and Pierre Corneille Namaharo.
- 8.2 Professor Leke gave a brief overview of 2023 applications reviewed by the IRC. She shared some observations noting strong progress towards more complete analyses and differentiated strategies for zero-dose & under-immunised children, but which remain lacking in clear methodologies. She expressed concerns over whether countries are optimising investments to improve Routine Immunisation (RI) coverage over time.
- 8.3 She observed that transformative gender strategies are becoming more common and could benefit from more guidance. In relation to applications for malaria vaccine, she noted that scale-up had been well targeted with best practices taking shape.
- 8.4 Finally, she concluded by outlining the IRC transformation work that is underway.

Discussion

- The PPC welcomed the update and emphasised the importance of the IRC's work.
- Several PPC members emphasised the importance of collaboration with the Global Fund, particularly on possible joint review processes and using the same applications that include joint indicators and monitoring processes. This would be particularly relevant for the malaria vaccine applications. The IRC Chair explained that discussions on efficiency were underway with the Global Fund's Technical Review Panel (TRP) with plans to continue these discussions on a quarterly basis. While joint applications used to exist through the national strategic plans, there is an opportunity to collaborate better, and simplify processes, while making sure that interventions are strategic and move the needle on the different indicators. It was noted that more work is needed to advance this planning.
- In relation to applications and country proposals, it was noted that these are largely prepared by outsourced consultants based in the Global South which allows for South-South knowledge exchange given that the same consultants work in different countries. It was acknowledged that this model could be enhanced and improved moving forward.
- In relations to campaigns and quality of routine immunisation, as Gavi considers providing cash support to countries to use across health systems strengthening (HSS) interventions as needed, the IRC was encouraged to assess whether

this would this provide incentives to countries to use some of these campaign costs towards RI.

- PPC members underlined the need to continue focusing on strengthening RI, building on innovative approaches and making the best use of available funds. The IRC has formulated some recommendations as countries have different approaches to identifying zero-dose children. Work is underway with WHO to put in place a harmonised and standardised approach with clear criteria to map out zero-dose children leveraging technology. The IRC will continue to document good practices which will be extended to countries through technical partners.
- Several PPC members expressed interest in hearing IRC reflections on in-country reviews of funding requests, given their link to ownership and country engagement. It was underlined that this has been part of the work on the IRC transformation, with more emphasis on differentiated approaches. In-country consultations have been efficient as they facilitate a holistic view on the programmatic level without affecting IRC independence in formulating key recommendations. It may occur that some countries push for specific asks, however, being on site helps the IRC in providing advice and guidance as to why some interventions are not value for money and/or not strategic.
- PPC members commended the gender-related considerations in the IRC analysis and enquired on gaps. It was noted that there was improved focus, and countries are using data and focusing more on identifying barriers. The importance of using available information to design country and context specific transformative interventions was emphasised.
- With respect to the positive examples of best practices highlighted in the report, PPC members expressed appreciation and asked that these findings be disseminated broadly to support countries learning from one another.

9. Vaccine Investment Strategy 2024: Investment Cases

- 9.1 Marta Tufet Bayona, Head, Policy, presented the investment cases, learning agendas and stockpiles proposed through the Vaccine Investment Strategy (VIS) 2024 process (Doc 09).

Discussion

- The PPC recognised the Secretariat and the VIS Steering Committee for the 18 months of rigorous and thoughtful work that had been done to prepare the recommendations.

- To clarify the PPC's position, it was requested to add an introduction to the recommendation to the Board to outline the complexity of the current public health landscape but also present the desire of the PPC to provide the necessary signaling to manufacturers at this point in time.
- PPC members noted the need to work with countries on prioritisation of vaccines given the increased number of vaccines and complexity. The Secretariat confirmed that it will work in coordination with Alliance partners in this respect.
- PPC members discussed the need to strike the right balance between early and late decisions for new vaccine investment and indicated that it would be important to consider future costs for Gavi 7.0 and 8.0.
- On value for money of the proposed investment cases, PPC members noted that the data in some cases is scarce and expressed the importance of generating more data through the proposed learning agendas.
- PPC members were comfortable with moving ahead with the recommendation for in-principle support for tuberculosis, dengue and group b streptococcus vaccine programmes, and associated learning agendas, as well as stockpiles and learning agendas for hepatitis E and mpox vaccines.
- The PPC was not prepared to recommend an in-principle shigella vaccine programme at this time but requested that the Secretariat revert with an updated investment case for a shigella vaccine programme when there is further information on country product preferences and timelines for technical guidance, policy and regulatory review processes, and in this regard wished to move ahead with a learning agenda on shigella.
- With respect to the mpox recommendation, PPC noted there was urgency to initiate the learning agenda and dose donation coordination activities in Gavi 5.1.
- The PPC was also supportive of discontinuing the COVID-19 vaccine programme following the completion of the current 2024-2025 programme.
- The PPC member representing the donor constituency cluster anchored by Norway asked that it be noted that her constituency cluster was not in agreement with the decision to go forward with the recommendation to approve in-principle investment cases for dengue and GBS. The PPC was therefore unable to reach consensus on recommendations b) and c) and the minority position expressed by Hannah Haaij on behalf of her constituency cluster would be reported to the Board in line with the PPC Charter.

Decision One

The Gavi Alliance Programme and Policy Committee (PPC) recognised that this Vaccine Investment Strategy (VIS) is taking place in a different global health and fiscal landscape with significant pressures on health systems, vaccination schedules and changing epidemiology due to climate change and urbanisation.

As the menu of vaccines available across the lifecourse increases, countries may require technical support to strengthen decision-making capacities on vaccine prioritisation and optimisation and support to strengthen their health systems to deliver them.

The PPC also recognised the importance of the VIS for long-term market signalling to manufacturers despite the many unknowns.

Considering this, the Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board, subject to the availability of funding for the 2026-2030 period following Gavi's replenishment for that period, that it:

- a) **Approve** in principle, support for a **tuberculosis (TB) vaccine programme**, contingent on the availability of a licensed product for adults/adolescents, outcomes of regulatory and technical review processes (including WHO prequalification and SAGE recommendation), and meeting the financial assumptions used as the basis for the TB investment case set out in Annex B to Doc 09;
- b) **Approve** in principle, support for a **dengue vaccine programme**, contingent on outcomes of regulatory and technical review processes and the availability and application of disease burden data in Gavi supported countries to inform the design of a vaccine programme, and meeting the financial assumptions used as the basis for the dengue investment case set out in Annex B to Doc 09;
- c) **Approve** in principle, support for a **group B streptococcus (GBS) vaccine programme**, contingent on the availability of a licensed product, outcomes of regulatory and technical review processes (including WHO prequalification and SAGE recommendation), and meeting the financial assumptions used as the basis for the GBS investment case set out in Annex B to Doc 09;
- d) **Note** continued exploration by the Secretariat of the need for, and design of, timely **market shaping interventions** aimed at ensuring that **TB vaccine supply** matches anticipated demand with minimal lag;
- e) **Note** the expected public health impact of a future **shigella** vaccine programme in Gavi-supported countries and that continued vaccine development is important, and **request** the Secretariat to revert to the PPC with an updated investment case for a shigella vaccine programme when there is further information on country product preferences and timelines for technical guidance, policy and regulatory review processes;

- f) **Approve** the VIS learning agendas for 2026-2030 for **shigella, GBS, dengue and tuberculosis** as described in Annex B to Doc 09;
- g) **Approve** in principle, support for a **global stockpile of hepatitis E vaccines**, contingent on outcomes of regulatory and technical review processes (WHO prequalification), and meeting the financial assumptions used as the basis for the hepatitis E investment case set out in Annex B to Doc 09;
- h) **Approve** in principle, support for a **global stockpile of mpox vaccines**, contingent on outcomes of regulatory and technical review processes, and meeting the financial assumptions used as the basis for the mpox investment case set out in Annex B to Doc 09;
- i) **Note** the financial implications associated with the above approvals (taken as a whole) for **2026-2030** are expected to be approximately US\$ 56.7 million, comprised of approximately US\$ 32.9 million for vaccine and operational cost support and approximately US\$ 23.8 million for learning agenda and reporting activities;
- j) **Note** that the **routine COVID-19 programme will be discontinued** following the completion of the current 2024-2025 programme, and that support for COVID-19 in the event of a worst-case scenario would be considered through Gavi's pandemic preparedness, prevention and response activities;
- k) **Approve** the VIS learning agendas starting from **2024** for **hepatitis E and mpox** vaccines, as described in Annex B to Doc 09 and note that the financial implications associated with the above approvals for 2024-2025 are expected to be approximately US\$ 0.5 million, which the Secretariat will seek to absorb from the Board-approved budget for the 2021-2025 Strategic Period; and
- l) **Approve** from 2024, a role for the Gavi Alliance in responding to the ongoing mpox outbreak, including coordinating mpox dose donations in response to the ongoing outbreak in the Democratic Republic of the Congo and further potential outbreaks in surrounding countries. Building on lessons learnt from the COVAX Facility, this coordination role will be contingent upon favorable conditions, including the availability of resources, clear demand from countries, regulatory compliance, and reaching agreements that are actionable by all parties involved.

Julie Hamra (IFPMA) and Rajinder Suri (DCVMN) recused themselves and did not vote on parts a)-c), f)-h), and k) of Decision One above.

10. Gavi 6.0: Update on Design and Operationalisation

- 10.1 Johannes Ahrendts, Director, Strategy, Funding & Performance, provided an update on the Gavi 6.0 strategy design and operationalisation. He outlined the

three phases which were led by the Board and were informed by extensive country-centric consultations.

- 10.2 He noted that the Gavi 6.0 strategy will be an ambitious but also a realistic strategy in line with the Alliance 2030 vision, with a preliminary cost estimate of US\$ 11.8 billion over the 2026-2030 period.
- 10.3 Finally, he outlined the operationalisation phase with five working areas to operationalise Gavi 6.0 once approved by the Board, with high-level work starting in 2024-2025.

Discussion

- The PPC welcomed the consultative approach in designing the Gavi 6.0 strategy and confirmed its support of the overall design of Gavi 6.0 as well as the proposed approach to operationalise it. PPC members also welcomed the emerging Gavi 6.0 priorities and associated impact.
- PPC members emphasised the importance of reflecting country priorities and recommendations from the Togo workshop in early 2024. Some PPC members noted misalignment between these priorities and the April 2024 Board retreat outcomes. The Secretariat confirmed that the Togo recommendations had been shared with the Board prior to the Board retreat in April 2024. Further consultations are scheduled with Ministers of Health during the World Health Assembly week in May 2024.
- In relation to the preliminary funding estimates, some PPC members encouraged the Secretariat to ask for an ambitious budget, particularly in view of new vaccine introductions and planned investments. Other PPC members expressed concerns on scale back on health systems funding discussed at the Board Retreat. The Secretariat clarified that the amounts shown are indicative strategic estimates which will be adjusted after the replenishment with more discussion to follow during the operationalisation phase. Potential impact on targets will be further developed into the operationalisation phase when designing the monitoring framework.
- Several PPC members underlined the importance of equity and Primary Health Care (PHC) investments and requested clarity on the support which would be provided to immunising older age groups beyond infants. PHC integration challenges related to the operating model were highlighted, particularly on resources and planning levels. The Secretariat noted that Gavi will aim to extend the reach of PHC services to missed communities through the zero-dose agenda and underlined its commitment to address planning and management challenges at the country level through different non-financial levers.
- Several PPC members underlined the importance of accelerating access to measles-rubella Micro-Array Patches (MR-MAPs) if additional funds become

available, or as part of the innovation agenda. The Secretariat referred to the Board guidance not to make additional investments in MR-MAPS at this stage.

- In relation to collaboration with new partners, PPC members stressed the importance of building on existing partnerships and engaging with non-governmental actors particularly in fragile settings, and the importance of the Lusaka Agenda. The need for a holistic review of the roles of Alliance partners and the Gavi Secretariat, and to clearly articulate what Gavi would fund through the Partners' Engagement Framework (PEF), was highlighted.
- In relation to the sub strategies, the Secretariat noted a suggestion to consider a specific approach for prioritisation of vaccines through policy levers and country envelopes that countries may be interested in prioritising. As part of the HS Strategy, the Secretariat would also look into operational costs of campaigns and consider how to best provide incentives for conducting quality campaigns in countries.
- On the operationalisation of the separate policies, one PPC member highlighted that the programmatic elements and the vaccine funding policies must interact in a coherent way to achieve impact. The Secretariat was called on to consider the transition of the Global Polio Eradication Initiative (GPEI) in the operationalisation process.
- In responding to PPC comments on the trade-offs on immunisation touch points, the Secretariat clarified that US\$ 1.6 to US\$ 1.7 billion would be allocated for HSS in Gavi 6.0 compared to US\$ 1.9 billion under Gavi 5.0. This reduction is driven by efficiencies requested by the Board in the consolidation of funding levers and a reduction in support for higher performing countries. The Secretariat would seek to support countries to achieve the same level of ambition through greater efficiency. The funding envelope at this stage would not allow for activities beyond guidance, technical assistance and learning support for the adolescent platform.
- The Secretariat noted that addressing vaccine hesitancy and gender-related barriers will continue to be a big focus under Gavi 6.0 and explained that broader health workforce strengthening is beyond what Gavi can address on its own.
- Regarding the approach on fragility, conflict and humanitarian settings, the Secretariat explained that it will be developing a more detailed approach which would be more deliberate on what Gavi will be trying to achieve in these settings aligned with country priorities with emphasis on flexibility in managing grants, underpinned by the right partnerships on the ground.
- In reference to PPC comments on Pandemic Prevention Preparedness and Response (PPPR) and global health security, the Secretariat noted that the Board approved PPPR approach emphasises agility in outbreak response. Clarity on the role of Gavi in setting up vaccine access mechanisms to address expected supply constraints in health emergencies will be critical to ensure that

an appropriate procedure is in place for Gavi to respond quickly to any future outbreak or pandemic.

10a Future of Gavi's Eligibility, Transition and Co-Financing Model and Middle-Income Countries Approach

10a.1 Benjamin Loevinsohn, Director, Immunisation Financing and Sustainability, presented an update on the future of Gavi's Eligibility, Transition and Co-Financing Model (Doc 10a). He referred to the existing ELTRACO Middle-Income Countries (MICs) model that can be built on for Gavi 6.0. He provided a brief overview of a set of shifts that would be prioritised by the future ELTRACO model, and further outlined the impact of updating the eligibility threshold on countries' transition pathway and eligibility.

10a.2 Adriana Jimenez Cuen, Director, Middle Income Countries, outlined how the MICs approach would become the catalytic phase of the new ELTRACO model, and laid out prioritised objectives under this phase.

Discussion

- The CEO provided introductory remarks underlining the impact of co-financing increases on countries' ability to meet their co-financing obligations. She also underlined reputational risks and the importance of messaging to countries that the enhanced ELTRACO model under the Gavi 6.0 strategy aims to invest in sustainability as opposed to reducing country support.
- The PPC broadly supported the 'direction of travel' for this workstream proposed for Gavi 6.0, with detailed design choices to be further explored as part of the Funding Policy Review (FPR). PPC members indicated that the FPR should pressure test the model's ability to address the affordability challenges of countries in Gavi 6.0 and put a particular focus on the future eligibility indicators and threshold, while also being cognisant of Gavi's ability to finance the model.
- The PPC emphasised that the proposed enhanced ELTRACO model could have consequential implications on Gavi 6.0, specifically on health impact, equity, sustainability, and market shaping.
- One PPC member representing implementing countries reiterated the need to conduct a more in-depth analysis of the proposed model, and to provide granular data on the impact of any co-financing increase on countries and cost drivers.
- The PPC supported the proposed learning agenda in Gavi 6.0. A proposal was made to pilot a policy with incentives that would stimulate an incremental transition by vaccine, or increase in government domestic spending by vaccine.

Some members suggested exploring a means to incentivise countries to invest and budget for HSS post transition.

- In reference to updating Gavi's eligibility threshold, while there seemed to be comfort among most PPC members on the direction of travel towards adjusting the threshold upwards towards US\$ 2,500 to help address financial sustainability and avoid case by case exceptions, the PPC requested granular country specific data against the different threshold scenarios, and some PPC members also noted concerns. Furthermore, most PPC members supported reintroducing vaccine support for previously self-financed programmes for countries regaining eligibility or re-entering preparatory transition.
- The PPC underlined the need for further analysis during the FPR on defining the specifics of Gavi vaccine support for previously fully self-financed vaccine programmes.
- The PPC emphasised the need to slow down co-financing increase in preparatory transition countries.
- In relation to providing minimum support for new vaccines introductions to countries in accelerated transition, the PPC underlined the necessity to further analyse and concretise the number of years and vaccine programmes for which additional support should be granted.
- The PPC expressed general support to decoupling the transition from vaccine and cash support for countries at risk of unsuccessful programmatic transition. The PPC underlined the need for defining a programmatic indicator to complement GNI per capita for decoupling – such as disease burden, level of mortality, or number of zero-dose children in countries – and stressed the need for further analysis on this during the FPR.
- The PPC supported the proposed shift to differentiating co-financing rules for a subset of fragile countries facing humanitarian crisis, noting the need to define criteria for fragile countries to multi-year waivers, and/or gradual co-financing ramp-up.
- With regards the proposed evolution of the MICs approach - the new 'Catalytic phase':
 - On Objective 1 (Drive sustainable introduction of key missing vaccines), there seemed to be some comfort that former and never Gavi countries should be eligible (needs-based) Further work would be needed via FPR on vaccine access and sustainable vaccine prices for MICs;
 - On Objective 2 (Prevent and mitigate backsliding), there was an early view that both former Gavi and Never Gavi MICs should be eligible (needs-based) to access global and regional 'public goods,' e.g. global TA platforms, regional peer learning, UNICEF's MICs Financing Facility

(MFF). Only selected former Gavi MICs should be eligible (needs-based) for Targeted Interventions at country level; and

- On Objective 3 (Ensure support for fragile countries), there seemed to be some comfort that former Gavi MICs should be eligible (needs-based); however, there was no consensus on never Gavi countries. Further exploration is needed through FPR of fragility support for never Gavi countries; and feasibility of support within a US\$ 250 million envelope.
- The eligibility to the above objectives would be limited to countries that are International Development Association (IDA)-eligible and/or Low- and Middle-Income Country (LMIC).
- In responding to queries, the Secretariat underlined that further information on vaccine access and sustainable pricing for MICs as well as UNICEF's MFF would be provided during a technical briefing before the June 2024 Board meeting and explained that the duration of the catalytic support would be time limited, tailored and focused. The Secretariat clarified that the cost implications on the fragility component would be US\$ 50 million and took note on of the PPC recommendation to explore this cost in the context of the strategic approach for Fragility, Conflict and Humanitarian settings.
- The specifics of the PPC deliberations on the proposed shifts and the new catalytic phase are included in Attachment B.
- The CEO noted the need for further deliberations on the concerns raised by the PPC and clarified that the Board at its meeting in June 2024, will be requested to approve the Gavi 6.0 one-pager and that any changes to the ELTRACO model and MICs approach will be approved during the operationalisation phase, following further consultations and PPC review.

10b Health Systems Strategy

- 10b.1 Sania Nishtar, CEO, provided introductory framing comments on her vision for Gavi's health system support. She noted that to date Gavi had not communicated well about its successes in this area and that despite strong work in pilot programmes, there was room to better connect the dots between the different pilots and seek ways to scale-up solutions. She indicated that she has now started to weigh in on the new directions that are envisaged in the Health Systems Strategy and that her intention is to encourage the development of disruptive systems for immunisation and the use of technological innovations. She emphasised that this was one of her key priorities in her 180-day plan and noted the plan to set up a workspace in her office to think transformatively about end-to-end grant management and immunisation delivery systems.

10b.2 Alex de Jonquières, Director, Health Systems and Immunisation Strengthening, presented the early thinking and key shifts in the development of a Health Systems Strategy, including greater differentiation, streamlined funding architecture, and enhanced data visibility (Doc 10b).

Discussion

- PPC members expressed enthusiasm for the vision of innovation presented by the CEO and were broadly supportive of the objectives of a Health Systems Strategy and the shifts described in the paper, with a request to develop a comprehensive theory of change.
- In relation to differentiation, PPC members were broadly supportive of the approach and asked that the Secretariat explore designing this in a way that incentivises domestic investment in routine immunisation.
- PPC members supported consolidation of funding levers and a holistic approach and expressed interest in further analysis of an allocation formula approach. There was also a request to think about how to join up planning and incentives for campaigns as part of the HS Strategy.
- PPC members expressed strong concerns on the implications of a cut in HSS funding both with regards to existing programmes and the zero-dose agenda and asked that the Secretariat spell out what can and cannot be delivered with the reduced funding envelope.
- On touchpoints, PPC members recognised that Gavi may not be investing significantly outside infancy but asked that the Secretariat explore how this can be addressed through other levers such as advocacy, technical assistance and partnerships.
- With respect to measurement, the PPC gave a clear steer not to impose new indicators and that measurement should serve countries' measurement needs. At the same time, PPC members indicated that Gavi should be more deliberate in identifying what metrics are critical for countries to collect in order to manage their immunisation programmes and ensure that they prioritise investments in their HSS grants to be able to measure those indicators. Critical immunisation indicators should be reflected as part of cross-partner work being led by WHO that can help rationalise HSS metrics that are broader than immunisation.
- On partnerships, PPC members reflected that an Alliance-wide approach would be important, with clarity on how that might cascade to the country level. PPC members also gave a strong push to better align behind country plans with other GHIs.

10c Climate Change Approach

- 10c.1 In the interest of time, this item was taken as read (Doc 10c) and no comments were taken.

11. Day Zero Financing Facility for Pandemics: First Response Fund

- 11.1 Marie-Ange Saraka-Yao, Chief Resource Mobilisation & Growth Officer, presented the design of the First Response Fund of the Day Zero Financing Facility for Pandemics, following the Board's approval of the financing for the mechanism in December 2023 (Doc 11).
- 11.2 Derrick Sim, Managing Director, Vaccine Markets, Health Security, reviewed the proposed eligibility criteria, or triggers, for the First Response Fund.

Discussion

- PPC members commended the Secretariat for a consultative process in developing this innovative mechanism and appreciated that the design included clear criteria and technical assessment balanced with the possibility of rapid decision making.
- PPC members queried the objective eligibility criteria and whether it was preferable to include grade 2 in addition to grade 3 WHO-declared emergencies. It was clarified that grade 2 emergencies are region-specific and only become grade 3 if they become cross-regional. Without allowing for grade 2, a multi-country event within one region would not be eligible for the First Response Fund. However, it was highlighted that not all grade 2 emergencies would be considered as other criteria would be assessed. It was also clarified that Gavi would be working with WHO on data and surveillance to facilitate the assessment of eligibility criteria.
- Several PPC members asked for more detail on why the ratio between Public Health Emergencies of International Concern (PHEICs) and smaller emergencies has shifted in the proposal from 90/10 to 80/20. It was clarified that this was intended to introduce flexibility, retaining US\$ 400 million for PHEICs but keeping US\$ 100 million available for smaller outbreaks, but that this could be assessed and adjusted if necessary if agreed by the Board.
- With respect to the design of the First Response Fund, there was a question about whether the First Response Fund would be drawn down and regularly replenished. PPC members requested that this point should be clarified prior to the Board discussion on this topic.

- The PPC discussed the proposed use of the US\$ 50 million threshold set out in Gavi's Delegation of Authority Policy, under which level the CEO would be able to act quickly. It was clarified that this proposal was made with the intention to allow speed where it was necessary. The CEO also noted that in early discussions on design that she had indicated her preference that decision making not be solely at her discretion, but rather to rely on an internal advisory group within the Secretariat and that the process should adhere to the Delegation of Authority Policy.
- PPC members also requested further detail on how this initiative fits together with other PPPR initiatives. It was noted that this workstream is complementary with the work of the informal working group focused on PPPR and country needs (the XVAX network).
- With respect to which countries would be eligible, it was clarified that Gavi-eligible countries would be eligible for the First Response Fund.

Decision Two

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

Approve the specifications of the programmatic design of the First Response Fund of the Day Zero Financing Facility for Pandemics, including the Fund's programmatic parameters and eligibility criteria, as set out in Annex A to Doc 11.

Julie Hamra (IFPMA) and Rajinder Suri (DCVMN) recused themselves and did not vote on Decision Two above.

12. African Vaccine Manufacturing Accelerator (AVMA)

- 12.1 Marie-Ange Saraka-Yao, Chief Resource Mobilisation & Growth Officer, presented an update on the African Vaccine Manufacturing Accelerator (AVMA) as well as a mapping of dependencies that had been produced (Doc 12).
- 12.2 Derrick Sim, Managing Director, Vaccine Markets, Health Security, reviewed updates to the eligibility criteria set out in the revised AVMA term sheet. He also presented the key features of a draft Monitoring and Evaluation (MEL) Framework for AVMA.

Discussion

- The PPC recognised the impressive work that has been undertaken since the discussion on AVMA at the last PPC meeting.

- While several PPC members noted their disappointment to see that Contract Manufacturing Organisations (CMOs) would no longer qualify in many cases, PPC members acknowledged understanding the reasons for the amendment to the AVMA key terms to restrict their eligibility.
- PPC members noted that AVMA remains a long-term, high-risk endeavour; and highlighted the following areas for further consideration as they present both reputational and investment risks: i) demand, and ii) regulatory matters, including timeline for pre-qualification.
- PPC members welcomed the MEL Framework and indicated they would like to see joint accountability across partners, particularly in areas that fall outside Gavi's purview so that expectations are clear from the start, including WHO on regulatory matters and Africa CDC on demand. One PPC member asked that the process to update the MEL Framework be clarified.
- One PPC member noted that it will be important to embed decision-making through Gavi governance structures rather than the new AVMA bodies that are being created. The Secretariat confirmed that standard Gavi governance processes would apply to AVMA.
- PPC members raised key dependencies for AVMA including the capacity of chemical companies and their reliance on government support in terms of underwriting and providing subsidies.
- PPC members also requested for ease of use to list the eligible antigens within the AVMA key terms and to be explicit when they might be updated next.

Decision Three

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

- a) **Approve** the amendments to the key terms of the African Vaccine Manufacturing Accelerator (AVMA) as set out in Annex A to Doc 12;
- b) **Note** the AVMA Monitoring, Evaluation & Learning (MEL) Framework, including proposals for periodic course correction as set out in Annex B to Doc 12; and
- c) **Note** the Key dependencies as set out in Annex C to Doc 12.

Julie Hamra (IFPMA) and Rajinder Suri (DCVMN) recused themselves and did not vote on Decision Three part a) above.

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.
- 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
- Lakshmi Somatunga
- Eduardo Humberto Retes
- Mohamed Jama
- Hannah Haaij
- Rob Whitby
- Pavani Ram
- Hitoshi Murakami
- Julie Hamra
- Rajinder Suri
- Anne Marie Mbengue Seye
- Ngashi Ngongo*
- Sania Nishtar, Chief Executive Officer
- Hanna Nohynek

Committee Member Elect

- Cécile Billaux

Other Board members attending

- Francesca Manno*
- Alexandra Rudolph-Seemann*

Other guests

- James Hargreaves* (Agenda Items 1, 2 and 6 (in part))
- Rose Leke (Agenda Item 8)
- Pierre C Namaharo (Agenda Item 8)
- Bolanle Oyeledun (Agenda Item 8)

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
- Manuel Sierra, Special Advisor to the PAHO 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
- Vivian Lopez, Special Adviser to the Gavi Board Vice Chair
- Mary Gallagher*, Special Adviser, CSO constituency
- Lauren Franzel-Sassanpour* (WHO)

Gavi Secretariat

- David Marlow
- Aurélia Nguyen
- Marie-Ange Saraka-Yao
- Thabani Maphosa
- Derrick Sim
- Brenda Killen
- Ian MacTavish
- Johannes Ahrendts
- Hope Johnson
- Sally Dalgaard
- David Kinder (Agenda Items 11, 12)
- Quentin Guillon (Agenda Item 6, 9, 10, 10a-c)
- Richard Mihigo (Agenda Items 10, 10a)
- Adriana Jimenez Cuen (Agenda Items 10, 10a)
- Benjamin Loevinsohn (Agenda Items 10, 10a)
- Alex de Jonquières (Agenda Items 2, 6, 9, 10, 10a, 10b, 10c)
- Marta Tufet (Agenda Items 6, 9, 10, 10a-c)
- Joanne Goetz
- Lindsey Cole (Agenda Item 8)
- Nadine Abu Sway
- Meegan Murray-Lopez

*Attending virtually

Attachment B – Overview slides on enhanced ELTRACO model used in the PPC meeting

Overview of proposed shifts for the enhanced ELTRACO model (as of 16 May 2024)

Proposed shifts	Work in progress	Big open questions to be further explored in the Funding Policy Review (FPR) in second half of 2024
a Introducing price sensitivity in Initial Self Financing (ISF) countries	Yes	• n/a
b Updating Gavi's eligibility threshold	2'500 GNI p.c., and reintroduce Gavi vaccine financing support for previously self-financed programmes for countries regaining eligibility or re-entering preparatory transition Acknowledge model to be revisited for Gavi 7.0	• Confirm whether to maintain GNI p.c. as the sole eligibility indicator or to supplement it by another indicator (under shift e) • Concretise specifics of Gavi vaccine financing support for previously fully-self-financed vaccine programmes
c Slowing down co-financing increase in Preparatory Transition (PT)	Yes	• n/a
d Providing minimum support for new vaccine introductions in Accelerated Transition (AT)	Yes	• Concretise the number of years and vaccine programmes for which additional support should be granted
e Decoupling the transition from vaccine and cash support	Yes	• Define the programmatic indicators for decoupling
f Differentiating co-financing rules for a subset of fragile countries facing humanitarian crisis	Yes	• Define eligibility criteria for fragile countries to multi-year waiver and/or gradual co-financing ramp-up

2

Overview of the Catalytic phase (as of 16 May 2024)

	Work in progress	Big open questions to be further explored in the Funding Policy Review (FPR) in second half of 2024
Objective 1: Drive sustainable introduction of key missing vaccines	• Former & Never Gavi countries are eligible (needs-based) if IDA eligible and/or LMIC	• Further explore access to sustainable vaccine prices for MICs (e.g. MICs Financing Facility (MFF))
Objective 2: Prevent and mitigate backsliding	• Former Gavi MICs eligible (needs-based) if IDA eligible and/or LMIC • Never Gavi MICs have access to "public goods," e.g. global TA platforms, regional peer learning, MFF	• n/a
Objective 3: Ensure support for fragile countries	• Former Gavi MICs eligible (needs-based) if IDA eligible and/or LMIC • No consensus on never Gavi	• Explore fragility support for never Gavi countries • Feasibility of support within US\$ 250 million envelope to be explored
Total envelope	• US\$ 250 million	