

Gavi Alliance Programme and Policy Committee Meeting

18-19 May 2022

Global Health Campus, Geneva, Switzerland

1. Chair's report

- 1.1 Noting that the meeting had been duly convened and finding a quorum of members present, the meeting commenced at 09.04 Geneva time on 18 May 2022. Helen Rees, Programme and Policy Committee (PPC) Chair, chaired the meeting.
- 1.2 The Chair welcomed all participants and in particular welcomed PPC members who were attending their first PPC meeting: Sue Graves (Bill & Melinda Gates Foundation), Abdelkadre Mahamat Hassane (Implementing Countries – Francophone/Lusophone Africa), Lamia Badarous (Vaccine Industry – Industrialised countries), Saad Omer (Research & Technical Health Institutes), Jakob Ström (Donor Countries – Norway/Finland/Netherlands/Sweden) and Anne Marie Mbengue Seye (Civil Society Organisations (CSO)).
- 1.3 As the PPC Charter allows for any Board or Alternate Board members to observe Committee meetings, the PPC Chair welcomed the participation of Megan Cain and Francesca Manno (Canada/Italy/New Zealand/Spain/Switzerland) joining for part of the meeting and Anne Schuchat (Unaffiliated Board Member) who would be joining for part of the second day.
- 1.4 The Chair noted that she had exceptionally extended to those PPC members unable to attend in person, the ability to attend remotely.
- 1.5 The Chair noted that regrets had been received from Vikas Sheel (Implementing Countries – SEARO/WPRO).
- 1.6 In the context of ongoing efforts to strengthen the relationship between the PPC and the Evaluation Advisory Committee (EAC), the Chair welcomed James Hargreaves, EAC Chair.
- 1.7 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).
- 1.8 The minutes of the PPC meetings of 20-22 October 2021 and 12 November 2021 were tabled to the Committee for information (Doc 01b and 01c respectively). The minutes had been circulated and approved by no-objection on 2 March 2022.
- 1.9 The Chair referred to the PPC workplan (Doc 01d). Committee members were reminded that they may contribute to the workplan by raising issues with either herself or the Secretariat.

- 1.10 She mentioned that a discussion board had been made available on BoardEffect for PPC members to post their comments and questions prior to the meeting and thanked the CSO constituency for their submissions, noting that the platform had not been more widely utilised and encouraged PPC members to do so going forward.

2. CEO Update

- 2.1 Seth Berkley, CEO, welcomed the PPC to their first in-person meeting since the start of the COVID-19 pandemic. He reported the April 2022 Board retreat had provided an opportunity for discussions on Gavi's four strategic goals and recalibrated priorities in light of the impact of the COVID-19 pandemic and shifting global health architecture, noting that equity remained at the core of Gavi's mission.
- 2.2 He provided an update on key global developments, and highlighted Gavi's advocacy and resource mobilisation efforts for the COVAX Advance Market Commitment (AMC) as well as future pandemic preparedness.
- 2.3 Dr Berkley reported on key geopolitical uncertainties and disruptions impacting Gavi-eligible and former Gavi-eligible countries, notably in Ukraine, Sri Lanka, Laos, Afghanistan, and Myanmar. He referred to the ongoing crisis in Lebanon and Venezuela which would be discussed during the meeting (Doc 08).
- 2.4 In relation to the impact of the COVID-19 pandemic, Dr Berkley referred to the WHO estimates of 5 May 2022 indicating approximately 14.9 million excess deaths attributed to COVID-19 between 1 January 2020 and 31 December 2021. Reported cases and death in Gavi-eligible countries is much lower, which also reflects the decline in testing which is placing the identification of new variants at risk.
- 2.5 With respect to RI, while national immunisation coverage estimates for 2021 are not yet available, he noted country administrative data is suggesting continued disruption in 2021, including for most former-Gavi countries during this period. He reiterated the need to continue to support countries in maintain RI coverage, preventing further backsliding and catching-up on missed children.
- 2.6 He highlighted fiscal challenges, noting debt challenges experienced by Gavi-eligible countries. The estimated government health spending per capita is projected to decline in over 25% of Gavi countries by 2026, as compared to 2019.
- 2.7 In reference to Gavi 5.0, Dr Berkley highlighted the shift from strategic and operational alignment in year one to executing for impact in year two.
- 2.8 He also outlined key vaccine and diagnostic-related developments, and provided updates on Polio, Malaria, Human papillomavirus (HPV), measles outbreak and response, Yellow Fever, Cholera and Ebola outbreaks.

- 2.9 In relation to COVAX, Dr Berkley provided a brief update on COVID-19 vaccine coverage, supply and demand, noting that the COVID-19 Vaccine Delivery Support Temporary Steering Committee had met three times since being established by the Board in December 2021.
- 2.10 Dr Berkley noted the need to consider how the impact of the COVID-19 pandemic, and its learnings, will come together with Gavi's core 5.0 strategy and operating model from 2023 onwards. This integrated approach between Gavi 5.0 and COVAX is being referred to as Gavi 5.1, being the natural evolution of Gavi 5.0 and serving as a bridge period taking us into Gavi 6.0. As part of this integration, Dr Berkley noted that the intention would be to convert a number of temporary or consultant positions created for COVAX to staff positions, in line with the integrated approach and in order to retain the best talent.
- 2.11 He briefly touched on vaccine cost-sharing, and highlighted discussions on Gavi's role in Pandemic Preparedness and Response (PPR), which is featuring prominently on WHO, the Group of 20 (G20) and the Group of Seven (G7) agendas, together with the post-pandemic global health architecture for health emergency preparedness and response. He underlined that it would be critical that the Alliance continues highlighting Gavi's unique contributions and capabilities in this context.
- 2.12 Finally, Dr Berkley provided updates on the Gavi Secretariat and noted several new Gavi staff. He reported on new ways of working, the gradual plan to return to the office and the resumption of duty travel. He concluded by referring to several ongoing efforts to monitor and support staff health and well-being.

Discussion

- PPC members expressed concerns on RI coverage recovery and the increased number of zero-dose children noting that a deep analysis would be necessary once WHO/UNICEF Estimates of National Immunization Coverage (WEUNIC) become available. Focusing on sustainably reaching un- and under-immunised children, whilst ensuring Gavi resources are impactful with the help of the Civil Society Organisations (CSOs), was also highlighted.
- PPC members underlined the need to address vaccine hesitancy, increase vaccine confidence and demand, whilst considering vaccine wastage, and reiterated commitment to gender, as being at the heart of Gavi 5.0 and the zero-dose agenda.
- PPC members expressed concerns on the increased debt to Gross Domestic Product (GDP) ratio in Gavi-eligible countries. Dr Berkley referred to Gavi's ongoing work with the World Bank and The Global Fund on sustainable health financing as part of the SG3 Global Action Plan.
- Several PPC members expressed concern on the deterioration of country contexts impacting health, such as droughts, and underlined the need for flexible policies to respond to a more disruptive world.

- In reference to challenges highlighted in Myanmar, PPC members encouraged the Secretariat to consider a high-level visit to the country.
- In responding to a query related to supporting the Democratic People’s Republic of Korea (DPRK) with COVID-19 vaccines, Dr Berkley clarified that Gavi had been working with DPRK on RI for some time through partners on the ground. DPRK had been included in COVAX allocation rounds and the government had thus far declined the offer of COVID-19 vaccines. Efforts were ongoing to offer vaccines to the country.
- PPC members reiterated the importance of regional vaccine manufacturing capacities, particularly in relation to sustainability and global health security. Dr Berkley referred to existing partnerships with manufacturers in Africa, including Senegal, as well as noting that focus needs to be on appropriate planning, sustainability and healthy to ensure success.
- In relation to the global health architecture, PPC members highlighted that Gavi’s inclusion in discussions on future pandemics and preparedness is critical. In this regard, it was suggested that it would be useful to see how a closer link between Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi could be envisaged potentially through engaging with the PPC and/or Board.
- Several PPC members noted their concern as to overall Secretariat staff health and well-being and welcomed the appointment of a new Chief Operating Officer (COO).

3. Strategy, Programmes and Partnerships: Progress, Risk & Challenges

- 3.1 Anuradha Gupta, Deputy CEO, provided an overview on the implementation of the recalibrated Gavi 5.0 priorities, noting that equity remains Gavi’s organising principle.
- 3.2 Ms Gupta noted that, against the backdrop of the COVID-19 pandemic, some rephased priorities were beginning to gather momentum (Doc 03) with the target of 13 introductions having been exceeded in 2021, and the number of planned campaigns having also been met during 2021. However, the 2018 Vaccine Investment Strategy (VIS) remains deferred for the time being, with the earliest launch now forecast to be in 2024, and the HPV programme is poised for a relaunch per the discussions at the April 2022 Board Retreat.
- 3.3 She highlighted the continued disruption to RI as posing a risk to Gavi 5.0, with available country administrative data indicating a 3.8% decline in RI coverage as compared to pre-pandemic levels, with 70% of this decline driven by India, where COVID-19 vaccinations exceeded one billion, as well as current political instability and insecurity in Myanmar. Across the remaining countries, the average decline is 0.7% based on the available country administrative data, noting that the WUENIC estimates to be released in July 2022 would shed further light on the level of disruption.

- 3.4 Ms Gupta noted that disruptions to RI are more prolonged than originally anticipated, with the strong recovery in the latter half of 2020 not necessarily being maintained. This would unfortunately result in a higher number of zero-dose children in 2021, driven by two key factors, namely: i) coverage declines in key countries based on interim data, notably India, and ii) the constraints in the African region in keeping step with the annual increase in birth cohort.
- 3.5 Ms Gupta noted that the risk of continued RI disruption in 2022 remains high with many Gavi countries yet to ramp-up COVID-19 vaccination coverage, including large countries such as Nigeria, DRC and Ethiopia. These countries together account for nearly 50% of the birth cohort in Gavi countries.
- 3.6 Ms Gupta highlighted that reaching zero-dose children and missed communities in the five high-impact countries would be critical to reaching Gavi 5.0 targets. Ms Gupta highlighted that targeted strategies and tailored funding is needed in these countries, and highlighted some key areas of progress, including; i) subnational engagement to identify priority populations, and development of targeted strategies for migrant and urban populations in India; ii) development of zero-dose reduction operational plans (Z-DROP) in Nigeria; iii) Mashako Plan and social spending targets in DRC; iv) decentralised engagement with diverse partners and integrated MR/Polio campaign in Pakistan; and v) the integration of RI and COVID-19 vaccination, as well as multisectoral approaches in Ethiopia.
- 3.7 She highlighted some encouraging trends, including many countries adopting new integrated and innovative strategies in reaching zero-dose children and missed communities, and on co-financing, countries continued to meet their obligations with US\$ 161 million having been paid in 2021, making this the highest amount since the introduction of Gavi's co-financing policy. A lower than anticipated six countries had been granted exceptional partial or full co-financing waivers.
- 3.8 She observed that creating more resilient, sustainable vaccine markets remains a core focus for Gavi 5.0, noting that in 2021 the number of vaccine markets exhibiting acceptable levels of health improved from 10 to 11. Two markets, HPV and Oral Cholera Vaccine (OCV), continued to exhibit unacceptable levels of market health in 2021, noting that the one-dose recommendation from the Strategic Advisory Group of Experts on Immunization (SAGE) guidance on HPV is expected to positively impact the supply situation. Two markets, Pneumococcal and Rotavirus, experienced supply constraints in 2021 which were successfully mitigated, although there continues to be a high risk of supply interruptions for Rotavirus, with the situation being closely monitored.
- 3.9 Ms Gupta emphasised continued monitoring of progress and risks for Gavi 5.0 amid ongoing uncertainty. She observed partner performance under the Partnership Engagement Framework Targeted Country Assistance (PEF TCA) had lagged behind Gavi 4.0 with only 68% of milestones achieved in 2021.
- 3.10 Following a request from the Board at its April 2022 retreat to hear more from Alliance Partners, Ms Gupta handed the floor to Kate O'Brien, Director

Immunization, Vaccines and Biologicals Department, WHO, and Ephrem Lemango, Associate Director Immunization, UNICEF.

- 3.11 Dr O'Brien outlined key priorities for WHO as an Alliance partner, particularly in leveraging COVID-19 pandemic investment across three-level coordination (global, regional and national) for recovery and strengthening of RI and COVID-19 vaccination integration. She noted that activities across RI and COVID-19 pandemic were both distinct and intertwined and pointed to a number of examples in the presentation.
- 3.12 On providing support to the National Immunization Technical Advisory Groups (NITAGs) she noted WHO had built out a comprehensive model for country capacity development through, for example, providing high quality resourcing at global level, regional level training and networking in ensuring collaboration between smaller countries, and at national level, access to resources for evidence gathering purposes. She highlighted the Immunization Act (2016), as promulgated by Nepal, as one of the first countries in guiding NITAG composition, membership and rotation through legislation.
- 3.13 Dr O'Brien outlined the innovative, digitally enabled approaches currently undertaken through, for example, the implementation of electronic immunisation registries for data quality improvements, the advancements in geospatial technologies for service delivery and the use of real-time stock monitoring tools to effectively redirect stock flows.
- 3.14 In terms of partner work, she highlighted the Pakistan National MR campaign, the largest campaign in administering vaccines within a short span of 12 days, where WHO had provided microplanning, training, readiness assessments and monitoring, and surveillance management and support for adverse events following immunisation (AEFI).
- 3.15 Dr Lemango continued by outlining UNICEF's ongoing investment in innovative data solutions, new tools and guidelines enabling governments to focus on vaccine equity and reaching zero-dose children. He highlighted UNICEF's response and recovery support following a number of outbreaks, including various tools for health system strengthening, such as the use of Thrive360 in supporting 62 countries in tracking COVID-19 and RI vaccine stocks, and the deployment of 83 Vaccine Management Specialists (VCM) in 38 countries to strengthen stock management (also through Thrive360).
- 3.16 He noted UNICEF's ongoing work in social and behaviour changes in supporting Gavi 5.0, strategic goal 2 (SG2) in reaching zero-dose and missed populations, notably by way of: i) application, scale-up and institutionalisation of Human Centred Design (HCD) approach to vaccine demand (14 countries currently supported); ii) social listening and digital engagement (soon-to-be-implemented Cranky Uncle application); and iii) tailored interventions developed through HCD in four countries to address gender norms. UNICEF continues to seek ways to leverage COVID-19 vaccine roll-out in strengthening immunisation and primary health care through an integrated approach across the health workforce, service delivery, health information systems, vaccine access, financing and governance.

3.17 Dr Lemango concluded by highlighting the acceleration required in implementing strategies to address both existing immunity gaps and build back beyond pre-pandemic levels. He noted recovery immunisation programme strategies using the Primary Health Care approach in facility screening at every health contact (to reduce missed opportunities) and promoting catch-up vaccination campaigns.

Discussion

- PPC members thanked the Secretariat and Alliance Partners for the rich presentations and were encouraged to observe progress and sustained focus at global and country level in advancing Gavi 5.0 strategy, particularly in a challenging time of global uncertainty.
- Several PPC members expressed concern in being unable to trace clear links and interactions between the Alliance partners, particularly in the areas of strategic and operational interface. PPC members felt an overall approach emphasising partner and data coordination, challenges and results, as well as local partner engagement, would bring clarity. They highlighted the need for better coordination in the presentation of materials by Alliance partners and suggested an integrated template, with country examples, would aid in demonstrating this. One PPC member mentioned it would be helpful to receive information on documented best practice, as well as details and results in the intersection of countries, communities and non-governmental organisations (NGOs) at country level.
- Alliance Partners agreed on the need for further clarity in presentation, and emphasised the principles followed in partner coordination and collaboration, including ensuring partner activities are based on comparative advantage, country impact and efficiency, prioritisation and country-level tailoring.
- The Secretariat clarified the role of country-level partners as equipping and supporting countries in programme delivery. The PEF TCA (Partners' Engagement Framework Targeted Country Assistance) empowers countries in determining partner combination and coordination, as well as partner diversification, noting one partner alone cannot fully support a country in achieving its ambitious goals. It was noted that local partner mobilisation is key in achieving the target of 30% resource allocation to local partners.
- With reference to the data on country backsliding, one PPC member expressed concern as to the quality of the data, whilst noting that the best approach to preventing outbreaks is to maintain a steadfast focus on reaching zero-dose children in a consistent manner.
- With respect to HPV vaccination coverage, the Secretariat recognised the distinct challenges in progressing in this area, noting the implementation urgency whilst simultaneously considering latest SAGE guidance and how this will be implemented at country level. It was noted that a holistic update on the HPV programme will be shared with the PPC at their next meeting.

- On vaccine equity and coverage, the Secretariat outlined that within Gavi-supported countries, nearly 16 million children are under-immunised (DTP3), and over two-thirds having not received a first dose (DTP1). The communities with these un- and under-immunised children are obviously at greater risk of outbreaks.
- Responding to PPC comments on country capacity and ownership, the Secretariat had observed improvements in Gavi 4.0 following intentional efforts in bolstering capacities and bringing in new supporting partners. Following PPC guidance, the Secretariat had implemented methodologies to consistently assess countries' management capacities and track improvement trends. Upcoming survey results are expected to reflect the COVID-19 pandemic impact including a requirement for re-energised efforts in supporting country leadership and management capacities.
- One PPC member encouraged the use of long-term forecasts as a tool in taking calculated risks, noting yellow fever as an example in tracing early assessment to mitigate potential supply disruptions and increased capacity needs assessments. On the new polio detections, further discussion on the role of hexavalent vaccine in supporting polio eradication was encouraged, as well as the efforts in leveraging resources and tools.
- Responding to comments on vaccine switches, particularly the rotavirus vaccine, the Secretariat highlighted this as an exceptional scenario following product discontinuation and supply interruption, with Alliance partners experiencing acute challenges in country adaptation to a new, more complicated vaccine. The Secretariat noted the distinction in routine and emergency vaccine switches.
- In relation to funding flows through country system, whilst noting the Board-approved target of 55% by the end of the strategic period, the Secretariat confirmed an implementation plan is in place and a detailed PPC update due in May 2023.
- Finally, PPC members suggested, considering the upcoming evaluation of the Independent Review Committee (IRC), that the Secretariat take the opportunity in re-evaluating IRC efficacy, with a view to fine-tuning agility and relevance.

4. COVAX: Key Strategic Issues

- 4.1 Aurélia Nguyen, Managing Director, Office of the COVAX Facility and Thabani Maphosa, Managing Director, Country Programmes, provided some introductory remarks on this item (Doc 04). Ms Nguyen provided an update on COVAX Facility operations, the role of the COVAX Facility in vaccine delivery through to 2023, and evolving COVAX vaccine policies, particularly the position on support for paediatric COVID-19 vaccinations.
- 4.2 She highlighted the rightsizing between COVID-19 vaccine supply and demand as critical to the 2022 strategy and flagged the risk of vaccine wastage, as well as the

need for flexibility within the Secretariat in updating its COVID-19 programmatic positions considering the evolving SAGE COVID-19 recommendations. She noted progress on the integration of COVAX into Gavi's core organisational structure and programmes.

- 4.3 Mr Maphosa outlined the importance of the SAGE recommendations in focusing COVID-19 vaccinations on highest priority populations, noting country aims in reaching both priority-use groups and other target groups. Highest-priority populations were still not systematically reached, particularly in Africa and Middle East / Central Asia regions.
- 4.4 He explained that the COVID Vaccine Delivery Partnership (CoVDP) had focused on 34 countries for concerted support in 2022, and was currently on track to reach ~21% coverage by end 2022, and potentially ~ 40% by mid-2023. He also pointed out innovations and investments to be leveraged for RI, in the context of programmatic integration, such as cold-chain storages remaining in place in a number of countries, continued training for healthcare workers, bundling of services and connecting with partners, such as The Global Fund, in reaching immunocompromised populations.
- 4.5 Ms Nguyen explained the demand and supply actions in meeting national targets and balancing the portfolio, whilst maintaining the ability to react to an upswing in the COVID-19 pandemic and minimising vaccine expiry. To date, 1.3 billion COVAX doses were already shipped (with ~2% wastage).

Discussion

- PPC members highlighted a clear strategy was needed for the evolution of Gavi's role in COVID-19 vaccine funding and delivery, in the context of Gavi 5.1.
- The PPC endorsed the proposal to continue administration of the COVAX Facility by Gavi through to the end of 2023, noting that going into 2023 continued updates would be required.
- The Secretariat emphasised the importance of clarifying further TA (technical assistance) needs to support countries in delivering COVID-19 vaccines, to ensure effective allocation of resources, rather than pursuing extending resources without clear engagement on understanding and purpose. The Secretariat emphasised the need for COVID-19 Delivery Support (CDS) to drive vaccine delivery as effectively as possible.
- In relation to future geographical scope, it was noted that it is not envisaged that self-financing participants be supported into 2023, although should there be a COVID-19 pandemic resurgence, this support may be reconsidered. In such an instance, and if required, the Secretariat would review any potential modalities for Gavi to provide support for these countries with COVID-19 vaccines and revert to the PPC and Board with a proposal on funding and eligibility.
- On the PPC's request to understand the approach to transition to Gavi 5.1, the Secretariat shared that it has started exploring how COVID-19 vaccinations and

learnings will come together with Gavi 5.0, recognising that some of the innovative and exceptional processes developed in the COVID-19 context would either need to be retained and brought into alignment with core processes, ramped down over time, or kept ready to deploy if needed for COVID-19 or in the context of a future pandemic.

- In relation to the proposal to delegate to the CEO the authority to adapt programmes based on evolving SAGE recommendations for COVID-19, the Secretariat explained that recommendations on paediatric vaccinations and shifting guidance on additional booster doses is expected to emerge ahead of the PPC meeting in October 2022. Together with sufficient doses and funding in place, the CEO will have appropriate authority to align COVAX support to SAGE recommendations.
- While one constituency initially supported Option 1 to allow for wider eligibility, consensus was reached for the PPC to support Option 2 to continue limited provision of paediatric COVID-19 vaccines and made some comments/observations:
 - Close alignment on updated roadmaps and ongoing landscape changes, balanced with country requests, would ensure favourable implementation;
 - Considering some countries were already falling behind in the overall COVID-19 vaccination agenda, particularly in Africa, one PPC member cautioned against proactively raising paediatric doses with countries and advancing too rapidly in this area; and
 - Concerns were raised that in attempting to reach the WHO 70% COVID-19 vaccination target, some countries were already progressing to vaccinate their paediatric populations, while still lagging behind in coverage for higher priority populations.
- Several PPC members commented that COVID-19 vaccine misinformation should not be underestimated, especially as some population sectors were refusing to take up vaccinations.
- Responding to the observations, the Secretariat reinforced the important emphasis on coverage of high priority populations. Where countries indicate their desire to implement COVID-19 paediatric vaccinations, the Secretariat reiterated the need for clear and careful engagement to continue to prioritise these high priority populations.
- In reflecting on the current programme roadmap and longer-term design, the Secretariat reiterated one PPC member's observation on
 - the importance of distinguishing COVID-19 vaccination roll-out as a means of controlling the COVID-19 pandemic, in contrast to the integration of COVID-19 vaccinations into the routine paediatric vaccination process.
- The Secretariat noted PPC comments on the importance of guardrails.

- Referring to the WHO-defined base, best and worst case COVID-19 pandemic planning scenarios, the Secretariat noted, in response to comments from PPC members, that although the base case scenario has been applied in current planning, there is awareness of potential fluctuations towards either of the two remaining scenarios. Whilst new procurement and new vaccines may be needed in a worst-case scenario, it may be determined in a best-case scenario that Gavi's support for COVID-19 vaccination programmes would cease.
- In relation to financial risks and implications around COVID-19 vaccine APAs, PPC members noted that the APAs have a higher risk profile as compared to a standard Gavi procurement process. The Secretariat agreed and noted the many risk mitigation measures and innovative financing arrangements.
- Noting PPC comments on CDS funding, the Secretariat explained the extent to which CDS funding had been over-subscribed and the need to raise additional funds in response to the request for support for COVID-19 vaccination roll-out.
- PPC members enquired as to the funding status of the Pandemic Vaccine Pool (PVP). It was clarified the PVP was established as a contingent financial mechanism for immediate response. On whether funds could be released from APA renegotiation, the Secretariat cautioned the potential difficulties, including timelines, particularly as some manufacturers are having to navigate their own governance processes and may require production costs audits before releasing funds.
- One PPC member expressed disappointment on the slow progress in delivery in the Humanitarian Buffer. The Secretariat acknowledged this as an important area for reflection, whilst noting eight country applications and no new applications as of December 2021. Encouragingly, of the 28 countries with a humanitarian response plan, 62% of COVID-19 vaccinations had been supplied through COVAX. Implementation strategy discussions were ongoing, and the Secretariat recognised engagement assistance from Médecins Sans Frontières (MSF) and International Federation of Red Cross and Red Crescent Societies (IFRC).
- Following one PPC member's request to fully understand the complexity of the COVID-19 vaccine supply and demand balance, the Secretariat explained the shift from a supply-constrained environment in 2021 to having adequate supply and a demand-dynamic environment in 2022 and only accepting donated doses once demand is confirmed. A monthly dose sharing forum, chaired by the CEO, with donor engagement, is tasked with coordinating donations for agile and diversified response to country requests, retaining additional flexibility in the event of a surge in vaccine demand in the event of new COVID-19 variants. Of the 1.5 billion COVID-19 vaccine donations committed, 600 million had been delivered, 400 million accepted and allocated, and discussions ongoing on the remaining 500 million.
- PPC members encouraged the Secretariat and Alliance Partners to explore ways to optimise CSO engagement, particularly in light of the next phase in delivery.

- One PPC member requested clarification as to whether COVID-19 vaccinations would require future Vaccine Investment Strategy (VIAS) process review. The Secretariat explained that given the VIAS review would only reach the Board for approval in 2024 (as part of Gavi 6.0 future antigens), consideration on the options for Gavi's role in future COVID-19 vaccine programme would be part of Gavi 5.1. The Secretariat reminded the PPC that in the 2018 VIAS cycle the Board had approved an epidemic framework to consider diseases and vaccines with epidemic or pandemic potential, out of cycle.
- At the invitation of the Chair, the EAC Chair shared information in relation to the COVAX evaluation as overseen by the EAC. He noted his encouragement in the enthusiasm expressed by the PPC in furthering PPC understanding of EAC activities and appetite for learnings around COVAX. Following EAC evaluation discussions in March 2022, independent evaluators considered it possible to undertake a multi-stage long-term COVAX evaluation, striving to be as complementary as possible with other relevant planned and ongoing evaluations and recognising the complexities associated with evaluating a still evolving programme. EAC discussions were ongoing on themes such as: i) evaluation of operational questions pertaining to fair and equitable vaccine distributions; ii) design decisions on COVAX governance and COVAX's approach to market shaping and risks; iii) understanding approaches and negotiations of supplier production and purchase agreements; and iv) understanding country engagement in the COVAX design implementation stage.

Decision One

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

- a) **Approve** the continued administration of the COVAX Facility by Gavi in 2023;
- b) **Delegate** to the CEO, with reporting to the Board, the authority to approve flexibility to adapt programmes based upon updated SAGE recommendations for COVID-19 (such as on vaccine use, additional boosters, the need for variant-adapted vaccines), contingent on available supply and funding;
- c) Informed by the interim approach outlined in Annex D to Doc 04, **approve** future paediatric support (July 2022 onwards) that supports continued limited provision of paediatric doses, with guardrails related to participant's coverage of COVID-19 vaccines in higher priority use groups and maintaining routine immunisation and monitoring any adverse impact on immunisation programmes.

Lamia Badarous (IFPMA) and Sai Prasad (DCVMN) recused themselves and did not vote on part c) of Decision One above.

5. Gavi's Engagement in Pandemic Preparedness and Response

- 5.1 Dr Berkley, CEO, provided some brief framing remarks noting that at its retreat in April 2022 the Board had recognised Gavi's inherent role in pandemic

preparedness and response (PPR) and the importance of engaging in the discussions on the evolving architecture. He noted that in a world of ever-increasing pandemic threats, Gavi has a unique and important role to play as part of a networked approach across relevant partners. He highlighted Gavi's added value; i) building on over 20 years of immunisation experience; ii) providing a range of innovative financial and programmatic instruments; and iii) leveraging its expertise in market shaping. He underlined the importance of building on the COVAX experience and drawing on the lessons learned.

- 5.2 David Kinder, Director, Development Finance and Sanne Wendes, Lead, Design Operationalisation, Office of the COVAX Facility presented this item (Doc 05). Mr Kinder presented the Secretariat's end-to-end approach in delivering PPR based on the three specific areas outlined by Dr Berkley. He noted Gavi's programmatic and financing tools be mainstreamed into the international processes underway to reform the global health PPR architecture.
- 5.3 Ms Wendes highlighted Gavi's model as an important driver of manufacturing diversification. She highlighted Gavi's experience in market shaping for vaccines to be deployed in improving supply resilience, particularly in Africa. She outlined several areas where Gavi would be drawing on lessons learned from COVID-19 and COVAX as relevant for the PPR agenda.

Discussion

- On the global health architecture, the PPC noted ongoing global discussions on the right levers and instruments for PPR. The PPC underlined the need to focus on what current organisations and institutions can and should do, building on already existing assets, whilst noting concerns on the proliferation of new initiatives in this space.
- In relation to sharing the lessons learned from COVAX in a future PPR agenda, the PPC underlined the importance of assessing the outcomes of the independent COVAX evaluation before building on its tools – whilst also recognising that timing may be difficult – together with a robust Alliance discussion on what can be done differently for future pandemic preparedness.
- The PPC underlined the need to keep the Board closely involved in PPR work noting that some PPR work is inherent in Gavi's core business, but that there would be trade-offs to taking on additional areas of focus. The PPC suggested the Secretariat: i) provide a clear overview of activities within Gavi's core work relevant to PPR, ii) identify activities implemented in the COVID-19 pandemic as relevant for future PPR architecture; and iii) present any new ideas.
- The Secretariat noted the PPC's call for alignment with initiatives of the Global Fund and World Bank, together with other regional institutions, ensuring clarity on roles and responsibilities. The Secretariat was encouraged to present a cohesive narrative to the Board of Gavi's role in PPR relative to other multilateral institutions.
- The PPC encouraged the Secretariat to consider in the development of its PPR strategy multiple inter-related components, such as: Primary Health Care (PHC)

strengthening, mother and child health, social equity, education, women's empowerment, as well as considering less vaccine-specific approaches, including therapeutics and diagnostics, surveillance, data and communication.

- The Secretariat noted that the PPR strategy should be supported by learning and evidence in strengthening a robust design process, whilst clearly demonstrating Gavi's strong evidence and analytical bias in proving its experience to undertake initiatives and recognising learnings and challenges.
- Several PPC members highlighted the importance of taking a pro-active role in pandemic preparedness regardless of targeted age groups and terminology. The Secretariat noted that PPR is a continuum, given that outbreaks can turn into pandemics and that Gavi's prevention impact, through its core programmes, can be capitalised on.
- The Secretariat was encouraged to provide more details on the financial instruments that could be helpful in market shaping for PPR.
- The Secretariat referred to its engagement with stakeholders who had previously been part of unsuccessful vaccine manufacturing initiatives in Thailand and Africa. Noting that sustainability requires a strategic approach to the selection of antigens, the Secretariat outlined its approach as: i) pro-active engagement and sharing of experience and expertise to inform ongoing discussions; ii) assisting in designing financial instruments to support the entrance of new facilities into the marketplace; iii) elucidating Gavi's role in procurement; and iv) together with other stakeholders, providing a workable model.
- The Secretariat noted the PPC's recommendations to consider trade-offs between Gavi's core mission and PPR in consideration of new workstreams, and to provide greater clarity on associated budget and governance mechanisms.
- In relation to vaccine hesitancy and generating demand, the Secretariat was encouraged to conduct a deep dive into these challenges to better understand the behavioural aspects around immunisation, noting the importance of narrowing the gap between vaccine indifference and proactiveness.
- The PPC supported the Secretariat's proactive work with partners in supporting regional manufacturing capacities, sustainable business models and healthy markets, and made the following comments/observations:
 - Gavi's role should seek to manage potential conflicts of interests given its role as the largest vaccine procurement agency;
 - The importance of Gavi's early engagement with countries and other key stakeholder to identify priorities and risks and develop financial strategies;
 - The need to support technology transfer to enable regional manufacturers delivery of quality products; and

- The importance of ensuring that regional and the global markets remain attractive to innovators.
- With respect to Gavi's role in supporting regional manufacturing, the Secretariat highlighted the importance of considering markets that could benefit from vaccine diversification beyond COVID-19, taking into account vaccines currently available in need of greater supplier diversity in sustaining a healthy market, as well as vaccines for neglected diseases. Considerations, such as new entrants with higher unit cost than established suppliers, and established suppliers increasing prices on total global market volume decrease, should also be noted.
- PPC members gave a number of suggestions on PPR, including: i) the Secretariat prepare future scenarios (five to ten years) on divergent vaccine sources and usage; and ii) provide details on financial instruments, associated costs and scope.
- In relation to life course immunisation, several PPC members recognised Gavi's role, notably in HPV, Ebola and COVID-19 vaccines, and highlighted the need for continued discussions given Gavi's work having mostly focused on child immunisations. Other members highlighted the lack of primary health care for adults, noting the struggle to vaccinate the over 60-year-old populations. The Secretariat noted the ability to capitalise on the experience of adult vaccinations following COVAX and other core work, whilst considering platforms and integration beyond the immunisation space.
- One PPC member expressed concerns that the draft WHO white paper on pandemic response makes minimal reference to immunisation and noted that all past Public Health Emergencies of International Concern (PHEIC) that have been declared, except for Zika, have had vaccination as the central element of its response.

6. Funding Policy Review

- 6.1 Marta Tufet, Head, Policy and Santiago Cornejo, Director, Immunisation Financing & Sustainability provided introductory remarks related to the progress in reviewing Gavi's funding policies, specifically focussing on the Co-Financing Policy (Doc 06).
- 6.2 Mr Cornejo noted that following the 2019 Funding Policy Review initiative, the Secretariat had observed in carrying out its review and work around the Co-Financing Policy, potential trade-offs and decision points which would benefit from PPC guidance, particularly on: i) co-financing safeguards to support vaccine uptake for countries in initial self-financing and preparatory transition phases; ii) decreasing barriers for countries in accelerated transition phase to introduce new vaccines; and iii) a comprehensive planning approach. He noted that in-depth analysis and precise financial and country implications will be presented in the next phase of work. He mentioned that a technical briefing to the Board on the Funding Policy Review was scheduled ahead of the June 2022 Board meeting.

Discussion

- The PPC commended the Secretariat's initiative in reviewing the Co-financing Policy in anticipation of the fiscal difficulties countries would likely continue to experience because of the COVID-19 pandemic, alongside anticipated introduction of new, more expensive vaccines.
- In response to comments from PPC members, the Secretariat reaffirmed its commitment to simplifying the policy.
- On introducing co-financing safeguards in support of vaccine uptake, the PPC suggested that the Secretariat explore further and analyse all the proposed options, also to potentially consider a hybrid approach combining Option 2 and Option 3, extended transition periods and flexibilities.
- In balancing vaccine value versus vaccine pricing, one PPC member suggested that the Secretariat examine country priorities against cost-benefit analysis.
- In decreasing barriers for countries in accelerated transition to introduce new vaccines, the PPC requested clarity on areas such as the number of years that would be supported (including the rationale for the fixed five-year term), financing transparency and equity implications. One PPC member highlighted the Solomon Islands as an example with high coverage rates, that whilst scheduled to transition in 2023, is currently facing a critical decline in its fiscal macro-economic outlook.
- With respect to country co-financing incentives, the Secretariat acknowledged that by providing more co-financing subsidies to countries that spend less on health, Gavi could be seen as rewarding countries that spend less in this important area.
- On whether Gross National Income (GNI) continues to be relevant as an eligibility indicator, the PPC suggested a broader consideration in the context of overall health systems and vaccine value as more appropriate, whilst noting this widening approach is to be considered in Gavi 6.0.
- Following several PPC member comments on eligibility criteria for extension to transition timelines, the Secretariat clarified that for countries considered in scope for extension, these countries would need to meet certain thresholds for coverage (DTP3) and equity (DTP1), and following country assessment, together with partner consultation, be assigned the appropriate extension time.
- The PPC cautioned that any co-financing modifications could create difficulties for countries where such modifications are not fully understood. Lack of co-financing visibility could impact country comfort and confidence in making vaccine applications. The PPC emphasised the importance of technical support for operationalising any changes.
- The Secretariat confirmed their continued work with countries and partners, such as the Immunization Financing and Sustainability Alliance Task Team (IF&S ATT) in reviewing further analysis.

- On the link between pricing and co-financing, the Secretariat explained the care needed in not undermining transitioning country sustainability since Gavi no longer provides support once a country has transitioned.
- Expanding on this point, the Secretariat acknowledged that in enhancing co-financing sustainability, it was important to engage Ministers of Finance and other country stakeholders to align country level implementation and dialogue, whilst noting how co-financing fits into the context of national strategic planning. Links to relevant Global Fund policies on co-financing could be explored.
- The PPC expressed their support for taking a comprehensive approach to addressing annual fluctuations in co-financing, including campaign co-financing.
- One PPC member wanted to know the difference between a framework and a policy. The Secretariat explained the purpose of a framework, in the context of this item, is to provide description on the distinct funding policies in place, and the interlinkages and additional points creating a comprehensive framework. The framework descriptions facilitate a clear and simple policy. Given the instruments had grown organically over time, the aim was now to standardise.
- One PPC member noted their disappointment that the review of the Health System and Immunisation Strengthening (HSIS) Policy was considered largely completed given the strategic engagement into health system strengthening (HSS) approach did not appear to have been thoroughly explored. Noting there were no actual pain points in an earlier HSS review, the PPC member felt the Secretariat could lean in on analysis in establishing the successes and missteps, whilst recognising areas of improvement.
- PPC members agreed that this item could be placed on the consent agenda for the June 2022 Board meeting.

Decision Two

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

- a) **Grant** the Secretariat the authority to implement an approach to apply co-financing flexibilities, as described in Annex A to Doc 06 in countries facing severe fiscal distress and/or countries facing a humanitarian crisis, noting that this shift was approved by the Board in December 2019 for incorporation into Gavi's new funding policies; and
- b) **Note** the Framework for Gavi Funding to Countries.

7. Review of Fragility, Emergencies, Refugees Policy

- 7.1 Marta Tufet, Head, Policy, and Amy LaTrielle, Director, Fragile & Conflict Countries, provided introductory comments on this item (Doc 07), noting a

Fragility, Emergencies, Refugee (FER) Policy has been in place since 2012, and is now being reviewed to align with Gavi 5.0.

- 7.2 Ms Tufet outlined the key changes to the policy, including a revised classification for chronic fragility, a clear role in emergencies, and expanded scope to include all displaced populations.
- 7.3 Ms LaTrielle noted that the policy is part of a broader effort, already started in Gavi 5.0, in having a more tailored approach to engaging in countries facing fragility or conflict. This includes differentiated processes and incentivising partnerships with the right actors.

Discussion

- The PPC welcomed the revised policy based on the lessons learned from the previous policy and external evaluation findings, noting enhanced clarity, focus on speed and agility and addressing issues missed previously. The PPC commended the consultative process followed to review the policy, particularly the external, independent evaluation and comprehensive stakeholder engagement.
- The PPC highlighted the importance of addressing sub-national inequities in collaboration with UN partners and CSOs, particularly for territories outside government control, and for cross-border populations. For the June 2022 Board paper, the Secretariat noted the suggestion to include details on scenarios related to: i) the unwillingness of governments to intervene on behalf of some populations; ii) the refusal of government interventions; and iii) autonomous regions without government recognition.
- In relation to questions on countries such as Burkina Faso, Guinea and Mozambique currently experiencing subnational challenges, but not in the fragility list, the Secretariat clarified that the main avenue to address sub-national fragility outside of countries classified under the fragility policy, is the Gavi 5.0 equity and zero-dose agendas. The Secretariat reminded the PPC that the Board had approved US\$ 500 million to be made available through the Equity Accelerator Fund (EAF), to support countries in identifying and sustainably reaching zero-dose children, with a focus on targeted and tailored approaches. As part of this EAF, US\$ 100 million was earmarked to target zero-dose children in cross border, conflict and fragile settings in 11 countries across the Sahel and Horn of Africa regions, through humanitarian partnerships. The Secretariat agreed to closely monitor the evolving situation in the identified countries, remaining agile to required changes in the fragility list, whilst noting the fragile country list may be adjusted based on the agreed criteria as needed.
- Given the number of fragile countries in Gavi's portfolio continues to grow, one PPC member highlighted the need for Gavi 6.0 to move from a revised policy, with additional flexibility, to an adaptation in Gavi's policies and approaches and seek different ways of working.
- The PPC discussed at length the interlinkage between the FED policy and the proposed Middle-Income Country (MIC) Approach (Doc 08). Concerns were

raised on the third criteria for determining fragility which captures any contextual challenges that further limits a country from making progress. While relevant and needed for Gavi-eligible countries, some PPC members found it a catch-all to justify engagement with never-eligible MICs. It was confirmed that the FED Policy only applied to those countries eligible for Gavi support. This was further discussed under Agenda Item 8.

- PPC members supported the decision to fast-track approvals and disbursements in acute emergencies. Several PPC members underlined the proposed Gavi Emergency Declaration Team should align with existing emergency declaration grading mechanisms as used by WHO and the UN Global Health cluster. In reference to the classification for emergencies, the Secretariat noted the extensive consultations, particularly with emergency response and humanitarian organisations and confirmed the criteria and classifications aligned with those already in place. The role of the emergency declaration team would be to determine an emergency and mobilise Gavi's processes.
- The PPC encouraged incorporating learnings from the COVAX Humanitarian Buffer in operationalising the FED policy, including drawing on limitations and what could be done differently. The Secretariat acknowledged multiple challenges in this area, including indemnification and liability and political complexities at country level as impacting the agility of the COVAX Humanitarian Buffer. The hope was that, following an agreement with UN agencies, progress could be achieved.
- One PPC member suggested the Secretariat conduct a review on the increasing requirements for countries to be funded for vaccination campaigns which could lead to delays and potential outbreaks. This is particularly given the tensions between the higher risk appetite for campaigns as part of the FED policy, versus the lower risk appetite as part of ensuring high quality campaigns. The Secretariat noted this concern, and the need for further deliberations on vaccine campaign sustainability.
- The PPC underlined the importance of alignment of support and bundling of services amongst partners and different agencies in efficiently operationalising the FED Policy. In this context, the PPC encouraged the Secretariat to: i) reflect on the relationship between future pandemics and fragility, as defined; ii) consider definitions of Internally Displaced Persons (IDPs) and refugees; iii) stratify populations in need of vaccines including adolescent females, people with disabilities and pregnant women; iv) provide operational timelines; and v) provide country tailored plans including communications and training.

Decision Three

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

- a) **Approve** the revised Fragility, Emergencies and Displaced Populations Policy attached as Annex A to Doc 07; and

- b) **Grant** the Gavi Secretariat Emergency Declaration Team¹ the authority to waive the requirement for independent review for new funding as per the Programme Funding Policy. This will be only in time-sensitive situations, with the objective to swiftly disburse funding in acute emergencies on a no regrets basis, noting that the framework including guardrails under which the Emergency Declaration Team can waive the requirements for independent review will be defined by the Secretariat in the operational guidelines, along with requirements for retrospective reporting to governance bodies including the Programme and Policy Committee and the Audit and Finance Committee.

8. **Gavi's Approach to Engagement with Former and Never-Eligible Middle-Income Countries (MICs)**

- 8.1 Santiago Cornejo, Director, Immunisation Financing & Sustainability provided an overview of the MICs approach in addressing key threats to equity and sustainability, highlighting the inter- and intra-country equity challenges. He noted Gavi continues to deliver against approved objectives in supporting eligible-MICs as was approved by the Board in December 2020.
- 8.2 He highlighted that some MICs are experiencing fragility, including severe economic crisis significantly impacting health systems, and referred to events in Lebanon, Venezuela and Ukraine having brought issues facing MICs into sharp focus. He explained the country requests for Gavi support from Lebanon and Venezuela, recognising that the two countries are currently not eligible for support under the MICs approach.
- 8.3 He outlined the Secretariat's aims in achieving explicit outcomes of the MICs approach by 2025, reflecting on its clear focus on results and explained these outcomes, although ambitious, were realistic.

Discussion

- The PPC thanked the Secretariat and acknowledged the consultative process in shaping the policy, notably with the World Bank, referencing Gavi's added value in leveraging resources as a driving force to unlocking co-financing commitments, especially the focus on zero-dose children in Honduras.
- The Secretariat acknowledged PPC comments that the MICs approach be centred on country facing work, with clear links to sustainability and transition, whilst prioritising preventing and mitigating backsliding, reaching zero-dose children, and supporting the introduction of new vaccines. The Secretariat clarified that most resources would be channelled for country and regional level technical interventions. The proposed support includes vaccine catalytic financing.

¹ The Emergency Declaration Team is composed of MD Finance and MD Country Programmes, however in decisions requiring waving independent review, the Director of Strategy, Funding and Performance will also be part of the decision making, given their role as second line of defense for Gavi's review process.

- In relation to funding to purchase vaccines to provide full support for sustainable access to vaccines for MICs, the Secretariat clarified that this includes vaccine catalytic financing for 50% of the first target cohort, as a one-off incentive support for countries.
- One PPC member highlighted the importance of maintaining focus on Gavi's commitment on missed vaccine introductions and raised the importance of respecting principles around tiered pricing. Given that the strategy may potentially impact the global market health, it would be important to have clarity on how this will be accounted for in Gavi's market shaping roadmap.
- Given the medium and long-term implications of the several options presented under the MICs strategy for the Gavi 5.0 period, one PPC member requested an evaluation of results, and to ensure that there are no underlying assumptions of a continuation into Gavi 6.0.
- In relation to suggested resource allocations, one PPC member noted that vaccine purchase financing be borne by the countries. A country support plan was highlighted as critical to implementation alignment.
- On the proposed mechanism to strengthen peer-to-peer learnings and innovative financing, the PPC encouraged the Secretariat to leverage existing platforms, such as the MIC Financing Facility within UNICEF, as well as the vaccine procurement practitioners exchange platform.
- In relation to trade-offs, the Secretariat clarified that the proposal on fragility does not deviate resources from achieving the set targets on zero-dose children and backsliding and new vaccine introductions.
- In relation to fragile MICs, PPC members requested that the Secretariat define a clear set of rules under which dedicated support could be provided to MICs that face challenges caused by fragility, emergencies and displaced persons. A rules-based approach to responding to the needs of fragile MICs should determine the conditions under which countries that are eligible under the MICs approach can receive additional dedicated support towards maintaining RI programmes.
- Several PPC members encouraged the Secretariat to provide more clarity on the exit strategy, and where it is intended the Secretariat will draw the line given the number of countries moving into fragile settings. Clarity around policy parameters for MICs meeting GNI criteria, and those that do not, is required.
- Responding to PPC comments regarding country support, the Secretariat clarified that Ukraine meets the criteria to receive support under the MICs approach, but currently does not meet the conditions for dedicated fragility support. Sri Lanka is also eligible under the MICs approach, but also does not currently fall within the FED policy classification. Iraq and Libya may be classified in the same category, but are not currently eligible under the MICs approach.

- In relation to providing support to Lebanon and Venezuela, the PPC acknowledged the challenging contexts and the pressing public health needs in both countries, and provided the following comments/observations:
 - A robust policy that supports the consideration of proposals (such as Lebanon and Venezuela) without the need for exception requests, and country-specific Board approval requests;
 - The PPC recognised the difficulties in determining whether Lebanon and Venezuela meet the MICs eligibility criteria, noting that Lebanon’s GNI is likely to meet the criteria in July 2022 and that Venezuela currently has no World Bank income classification, making it difficult to assess;
 - Noting the impact to country immunisation programmes, several PPC members acknowledged the benefits of interventions in Venezuela and Lebanon;
 - Concerns that the proposal to support both countries would allocate up to a third of the package available to support fragile MICs, noting the need for a cap on such funding support, and the competing priorities of countries that meet the criteria for such funding;
 - The crisis in Venezuela is strongly linked to governance which highlights the question on sustainability of this support;
 - Initial discussions of in-country sovereign donors in Venezuela indicates Gavi as the mechanism to extend country support;
 - Leveraging Venezuela’s frozen assets (currently in excess of US\$ 40 billion) could potentially fund necessary support, although would require government and donor agreement;
 - The Secretariat clarified the request to support Venezuela and Lebanon had arisen through Gavi partners, and the Ministry of Health respectively;
 - One PPC member highlighted the difficulties in working with embargoed regimes, such as Venezuela, which would entail working with UN partners on the ground in implementing support, if any; and
 - The PPC underlined the importance of alignment and mapping of partner support in countries, particularly the UN specialised agencies such as the UN High Commissioner for Refugees (UNHCR).
- Noting the robust discussions and having found no conclusive path forward, the PPC agreed to have an extraordinary meeting prior to the June 2022 Board meeting to discuss a revised approach to supporting fragile MICs that would:
 - i) provide a clear framework in guiding Gavi’s support to countries such as Venezuela, Lebanon and other fragile MICs; ii) clarify any potential trade-offs of providing this support; and iii) clarify eligibility for dedicated fragility support as well as the conditions under which support would be provided.

9. Innovation Approach for Gavi 5.0

- 9.1 Quentin Guillon, Head (acting), Strategy, Performance & Transformation, provided some introductory remarks on this item (Doc 09) noting that since first engaging with the PPC in May 2021, the Secretariat had embarked on broader consultations across the Alliance, whilst also building on the Alliance's extensive experience, in enhancing Gavi's 5.0 innovation approach.
- 9.2 He highlighted the continued focus on supporting scale-up of proven innovations in country, alongside a more focused role on ensuring a clear 'path to scale' with engagement on 'Category 1' innovations needing proof of concept/adaptation at country level and 'Category 2' innovations needing global/regional interventions to be scaled-up. He noted the key shifts in the proposed approach, including ensuring innovation is informed by country needs.
- 9.3 The proposed US\$ 50 million additional HSS funding request would catalyse scale up of innovations in country by addressing a funding gap to support scale up of innovations in country, as well as increasing ownership and commitment.

Discussion

- Responding to a question on generating innovation interest and demand, the Secretariat explained encouraging country engagement through existing touchpoints in countries such as Full Portfolio Planning (FPP) processes or Joint Appraisals, as well as responding to ad-hoc country-driven requests. The Secretariat had also observed in-country innovation focal points beyond health ministers to include premier and innovation ministers.
- In relation to innovation sustainability and the extent the innovation budget is embedded within national country programme, the Secretariat highlighted the continued country dialogue on advocacy for increased domestic investment in immunisation as extending to innovation. The additional US\$ 50 million HSS investment is intended to strengthen dialogue, whilst also incentivising and supporting own country investment in innovation to drive sustainability and country commitment.
- In clarifying the potential SFA (strategic focus areas) and TCA overlap, the Secretariat explained the SFA as a key funding envelope for Category 2 innovations. The current SFA programming is ongoing with the focus shifting from business-as-usual activities to innovation investment, testing and scaling-up the more innovative approaches incubated at regional level, towards countries. TCA would support Category 3 innovations (Proven innovations ready for scale-up at country level), as it goes hand in hand with HSS investments.
- In relation to revamping the existing Innovation for Uptake, Scale and Equity in Immunisation (INFUSE) advisory group for Category 1 innovations, the Secretariat pointed to the inclusion of independent experts across technology, academia, Alliance Partners and donors, in reviewing and approving particular INFUSE investments, whilst noting the need for consistency and touchpoints through the process. Country representatives, including at ministry level, had previously

participated in assessing innovation applicability, providing important contributions in innovation scaling, and are encouraged to continue engagement. The Secretariat noted that increasingly INFUSE is regarded as a platform in building connections and dialogue at global, regional and national levels, particularly key in Category 1 innovations.

- The Secretariat acknowledged the need for a transparent innovation monitoring framework. In awarding and allocating the additional US\$ 50 million innovation spend through the usual HSS monitoring mechanisms.
- The Secretariat outlined the evolution of CSO engagement since establishing INFUSE in 2016, noting the CSO constituency as an INFUSE applicant and finalist. The Secretariat supported continued CSO engagement particularly observing CSO sourcing innovations and innovators from within country as a compelling touchpoint.
- The Secretariat noted to return to the PPC during the strategic period with updates on the broader innovation approach.
- PPC members agreed that this item could be placed on the consent agenda for the June 2022 Board meeting.

Decision Four

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

- a) **Approve** the overall innovation approach for Gavi 5.0 as laid out in Annex D to Doc 09;
- b) **Approve** US\$ 50 million in additional funding for Health System Strengthening (HSS) in Gavi 5.0 for countries interested in scaling proven innovations to be allocated, in accordance with the Programme Funding Policy, above HSS country ceilings on an exceptional basis.

10. Update on Malaria Vaccine Programme

- 10.1 Stephen Sosler, Technical Adviser, Vaccine Implementation, provided some introductory remarks on the progress made in the design of the malaria vaccine programme, as well as the options available for Gavi engagement in supporting and addressing the funding gap for Phase 2 of the Malaria Vaccine Implementation Programme (MVIP) (Doc 10).
- 10.2 He outlined the evolution of the various stages in the malaria vaccine regulatory assessments and advisory recommendations, noting Gavi's funding contributions along the way, including the Board's approval of approximately US\$ 156 million investment covering malaria vaccine purchases, TA and learning activities for the remainder of Gavi 5.0.

- 10.3 On programme design and progress, he noted the establishment of a multistakeholder coordination group, the Malaria Vaccines Coordination Team (MVCT), as an effective resource in finding solutions to problem areas. There were ongoing discussions with The Global Fund to find ways to reduce country burden for countries applying for support from both organisations, and to ensure technical assistance aligns with the notion of a comprehensive malaria control programme as an additional tool in a suite of effective interventions.
- 10.4 Finally, he noted that results of the UNICEF tender related to pricing and volumes is expected later in 2022 and is expected to further shape the malaria vaccine programme.

Discussion

- PPC members were supportive of the malaria vaccine programme, with one PPC member particularly delighted to see that after a substantial time in development, opportunities were beginning to take shape. Despite advancements, the PPC noted the limited supply and the importance for continued research on other potential vaccines.
- Several PPC members were concerned with the September 2022 application window being too narrow (i.e., there being a very short period between the first-time inclusion of a malaria-specific vaccine funding section in the Gavi vaccine funding guidelines (July 2022) and the close of the application window in September 2022). The Secretariat acknowledged that during the application window, countries may not have full visibility on the revised co-financing policy to facilitate in-depth country discussions on affordability and vaccine value, whilst also noting ongoing partner discussions on whether this window be limited to MVIP countries only considering the timing for securing the technical assistance and guidelines for full applications.
- It was noted that a potential way forward could be to prioritise MVIP countries, thereby mitigating any delays or interruption in continuation of existing implementation programmes, especially in light of supply, pricing and co-financing variables. The subsequent application windows (the one closing in January 2023 and those thereafter) could be opened up to countries that are not part of the MVIP and focus on country objectives in terms of coverage and population.
- One PPC member suggested the Secretariat consider vaccine cost-sharing (for level two applications) in light of potential limited supply. Noting COVID-19 vaccine cost-sharing at the time of limited supply and greater demand, the PPC member wondered if the same rationale would encourage countries in mobilising their own resources, as well as provide an indication of concrete demand.
- Responding to comments from PPC members, the Secretariat acknowledged the importance of a longer programme vision, clarifying its aims in designing a malaria vaccine programme, rather than an RTS,S vaccine programme. With this in mind, the Secretariat continues to engage in partner discussions in uncovering the best way forward.

- Noting PPC comments on vaccine supply constraints, the Secretariat reiterated the importance of working closely with Alliance partners in the market-shaping roadmap, aware that a thorough understanding of this roadmap ensures Alliance partner alignment on vaccine volumes and availability.
- The PPC member representing the Vaccine Industry - Developing Countries cautioned that following the 30 plus years in reaching the final stage in the RTS,S initial product development, and moving towards scale-up and large-scale manufacturing stage, country participation and introductions, that without a proper understanding of demand, determining volume will remain difficult. He noted the encouraging and continued progress in manufacturing investments, product development, clinical trials, technology transfers continue and increasing manufacturing capacities.
- In relation to the vaccine allocation framework, the WHO representative explained that the applications are welcome from those countries and their subregions with category 1 (highest) combined malaria and mortality burden. Additional criteria have been laid out in the allocation framework, and communicated to countries, to allocate vaccines among those applicants, if the total demand exceeds supply. PPC members encouraged a simplified application approach (such as the use of an Expression of Intent) which, in turn, could provide a sense of demand.
- On PPC comments around the introduction of new vaccines into more countries, the Secretariat acknowledged challenges in this area particularly in light of the fourth dose administered in the second year of life, whilst ensuring not to miss the opportunities to deliver on other services and vaccines. When considering vaccine targeting, the Secretariat acknowledged clarity in process as key when rolling out vaccines in the near- to mid-term, noting a sub-national targeted way as ensuring the most impact in the highest malaria burden.
- In respect of partner coordination, the Secretariat pointed to the good coordination between the Expanded Programme on Immunization (EPI) and the National Malaria Control Programmes in ensuring complementarity across interventions, noting also MVIPs having had time to form solid links with these bodies. When moving to the next set of countries, however, work will be needed to build these relationships and coordination, especially with small vaccine volumes.
- Responding to a PPC member's comment as to potential incorporation of Roll Back Malaria (RBM) as part of MVCT, the Secretariat explained this was being addressed and discussed with RBM as to whether they would wish to be included given their obvious value to the programme.
- The PPC highlighted the importance of clear and specific country communication. Communities must be able to clearly understand the importance of employing other control and preventative measures, on top of receiving vaccinations. The Secretariat explained the continued work with Alliance partners in both the public vaccine roll-out campaigns, as well as community level messaging.

- Referring to the lessons learned from the three-country pilot implementations, the PPC member representing WHO explained the relative lack of communication challenges in placing the malaria vaccine into routine EPI programming and the partner coordination experience, noting in particular that anticipated hurdles in coordinating with the National Malaria Control Programme (NMCP) were less than anticipated. The PPC member clarified the role of NMCP as one of determining where the high, medium and moderate transmission areas are for a new vaccine introduction into routine EPI programming, as is done for all subnational tailoring of malaria interventions, and re-emphasising the importance of maintaining other malaria control measures.
- PPC members agreed that this recommendation could be placed on the consent agenda for the June 2022 Board meeting.

Decision Five

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

- a) **Approve** an increase in the amount of funds for Phase 2 MVIP activities from US\$ 11.6 million to US\$ 12.25 million by allocating the Phase 1 underspend (US\$ 650,000) to be applied towards the previously approved Phase 2 activities; and
- b) **Note** that any underspend from the Phase 2 activities is to be returned to Gavi in accordance with the terms of the grant agreement.

Kate O'Brien (WHO) recused herself and did not vote on part a) of Decision Five above.

11. Review of decisions

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

12. Any other business

- 12.1 The Chair thanked PPC members for the rich discussions and involvement in terms of diversity of views, as well as consensus, and commended the active listening amongst members. The Chair acknowledged the Secretariat's hard work and quality of thought in the papers presented to the PPC.
- 12.2 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

- Helen Rees, Chair
- Awa Marie Coll Seck
- Sue Graves
- Michael Kent Ranson
- Kate O'Brien
- Abdelkadre Mahamat Hassane
- Kelechi Ohiri
- Bernard Braune
- Jakob Ström
- Susan Elden
- Naomi Dumbrell
- Lamia Badarous
- Anne Marie Mbengue Seye
- Seth Berkley, Chief Executive Officer
- Alejandro Cravioto (Agenda Items 1-8)

Committee Members (virtual)

- Ephrem Lemango
- Edna Batres (Agenda Items 5, 8, 9)
- Sai Prasad (Agenda Items 4, 9-12)
- Saad Omer (Agenda Items 2-6, 9-12)

Regrets

- Vikas Sheel

Other Board members attending

- Megan Cain (Agenda Items 4-5)
- Francesca Manno
- Anne Schuchat (Agenda Items 6-12)

Other guests

- James Hargreaves, Chair, Gavi Evaluation Advisory Committee

Observers

- Ruzan Gyurjyan, Special Advisor to the EURO constituency
- Rolando Pinel, Special Advisor to the PAHO constituency
- Pratap Sahoo, Special Advisor to the SEARO constituency
- Zaeem UI Haaq, Special Advisor to the EMRO constituency
- Oulech Taha, Special Advisor to the Francophone Africa Constituency
- Stella Villares, Special Adviser to the Gavi Board Chair

Gavi Secretariat

- Anuradha Gupta (Agenda Items 1-3)
- Jalaa' Abdelwahab (Agenda Item 10)
- Nadine Abu-Sway
- Johannes Ahrendts
- Hannah Burris
- Santiago Cornejo
- David Kinder (Agenda Item 5)
- Joanne Goetz
- Quentin Guillon (Agenda Items 2-4, 9)
- Hope Johnson
- Brenda Killen
- Amy LaTrielle (Agenda Item 7)
- Thabani Maphosa
- Meegan Murray-Lopez (Agenda Item 4)
- Aurélia Nguyen
- Tanya Robinson
- Marie-Ange Saraka-Yao
- Stephen Sosler (Agenda Item 10)
- Marta Tufet (Agenda Items 6-8)
- Sanne Wendes (Agenda Items 2-5)