

Gavi Alliance Programme and Policy Committee Meeting

18-19 October 2018

Gavi Alliance Offices, Geneva, Switzerland

1. Chair's report

- 1.1 Finding a quorum of members present, the meeting commenced at 09.05 Geneva time on 18 October 2018. Richard Sezibera, Programme and Policy Committee (PPC) Chair, chaired the meeting.
- 1.2 The Chair welcomed participants and noted that as he had to leave the meeting at the end of the first day to return to Rwanda to attend to important matters of the state he had requested the Secretariat to review the order of items to be discussed at the meeting, as per the revised agenda shared with PPC members the evening before. He also informed PPC members that he had asked Kate O'Brien to chair the meeting in his absence, which she had kindly agreed to do as such short notice.
- 1.3 The Chair noted that Helen Rees was joining the meeting by phone. He also noted that in the absence of Jason Lane, Danny Graymore, Board member for the UK/Qatar constituency, was joining the meeting in person, as was Irene Koek Board member for the US/Australia/Japan/South Korea constituency, in the absence of Susan McKinney. The Chair welcomed both Board members to take part in the discussions but noted that as observers, they would not be in a position to take part in the decision-making processes.
- 1.4 The Chair informed participants that Sylvie Briand from WHO would be joining for the session on Gavi Support for Yellow Fever Diagnostic Capacity and Michel Zaffran from GPEI would be joining for the session on Gavi's Support for IPV post 2020.
- 1.5 The Chair also informed participants that Dr. Ngozi Okonjo-Iweala, Gavi Board Chair, would be joining the meeting by phone for the afternoon of the second day.
- 1.6 The Chair referred to the survey which PPC members are invited to complete after each meeting. He noted that comments from the survey after the May PPC meeting were generally positive. He also noted that, in response to a request from the PPC, the questionnaire this time will focus more on interactions between the Committee members themselves and between the Committee and the Secretariat.
- 1.7 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).

- 1.8 The minutes of the PPC meeting of 2-3 May 2018 were tabled to the Committee for information (Doc 01b in the Committee pack). The minutes had been circulated and approved by no-objection on 31 August 2018.
- 1.9 The Chair referred to the PPC workplan (Doc 01c) and the Action Sheet (Doc 01d). He reminded Committee members that they may contribute to the workplan by raising issues with either himself or the Secretariat.

2. CEO Update

- 2.1 Seth Berkley, CEO, provided an update to the Committee covering key developments in the global landscape, updates on previous PPC discussions and Board decisions, as well as progress and challenges on implementing Gavi's current strategy and an overview of the key items for discussion at this meeting.
- 2.2 Dr Berkley noted that this was the first PPC meeting in the Global Health Campus and highlighted that the campus is providing opportunities to further collaborate within the Secretariat as well as with other global health organisation co-located in the campus.
- 2.3 He confirmed that updates on strategic progress, risks, and the Partners' Engagement Framework (PEF) have been consolidated into one report to provide a holistic view of performance against Gavi's 2016-2020 strategic goals.
- 2.4 Dr Berkley highlighted that the WUENIC estimates of immunisation coverage for 2017 had been released in July 2018, showing that Gavi immunised a record number of children in 2017 and that progress in DTP3 coverage had been seen for the first time in this strategic period. However, he also noted that progress needed to accelerate if Gavi is to meet its 2020 targets.
- 2.5 He noted that Gavi is making progress on the breadth of protection targets, despite on-going supply constraints. In particular, he highlighted that two main suppliers of the rotavirus vaccine have confirmed that they have insufficient supply to meet country demand in 2018 and 2019, and that the Alliance is urgently exploring actions to minimise the impact of this situation.
- 2.6 Dr Berkley also noted that, as previously discussed, supply constraints for the HPV vaccine continue meaning Gavi's goal of reaching 40 million girls by 2020 is at risk. He confirmed that progress is still being made with countries introducing the vaccine targeting only a single age group.
- 2.7 Dr Berkley highlighted that due to new country GNI per capita data being released by the World Bank in July 2018, Syria is now classified as a low income country and therefore eligible for Gavi support, and that Congo Republic has dropped below Gavi's eligibility threshold. He noted that the issue of Congo Republic's eligibility will be discussed further during this meeting (Doc 08).

- 2.8 Dr Berkley provided an update on some of the strategic developments in the broader landscape, including confirming that Gavi recently signed the 'Global Action Plan for Health Living and Well-Being for All' at the World Health Summit in Berlin. He mentioned that Gavi welcomes this initiative of President Akufo-Addo, Chancellor Merkel and Prime Minister Solberg, and supports this opportunity to strengthen collaboration across the global health community and help accelerate progress towards achieving the SDGs.
- 2.9 Dr Berkley provided an update on previous PPC discussions and Board decisions, including an update on Gavi's engagement in the Ebola outbreak in the Democratic Republic of the Congo (DRC), including the provision of investigational vaccines under the Advance Purchase Commitment with Merck. In addition, he provided updates on Gavi's support for cholera and yellow fever stockpiles, the EYE Strategy and Gavi's role as an observer to the International Coordinating Group (ICG).
- 2.10 Finally, Dr Berkley recalled that Gavi's Mid-Term Review (MTR) will take place at the end of the year in Abu Dhabi. It will be an opportunity to report back to donors on how Gavi is delivering against its investment case, and will provide a balanced view on Gavi's successes and challenges. Dr Berkley confirmed that the MTR report will be made available to the Board ahead of the Board meeting.

Discussion

- The rotavirus vaccine supply issues were discussed, including lessons learnt from a market shaping perspective. Dr Berkley confirmed that two Indian manufacturers now have pre-qualified products available, and that Gavi is currently exploring supporting countries to switch to alternative products. It was noted that this experience highlights the importance of products being developed with developing countries in mind at the beginning to make sure they are fit for purpose.
- In response to questions from PPC members, Dr Berkley provided an update on the process of collaborating with other global health agencies on the SDG3 Global Action Plan, and with the Global Fund (GF) and Global Financing Facility (GFF) on the '3Gs' collaboration paper. Dr Berkley reiterated that collaboration is at the heart of the Alliance model but also noted the importance of ensuring that collaboration is outcome focused and does not distract from the efforts of each agency to deliver on their core missions. He also highlighted that the challenge going forward will be to rapidly identify a set of concrete actions to enhance collaboration and clarify which agency is best placed to address any gaps identified, taking into account each agency's comparative advantage and resources.
- Further to a question on the current Ebola outbreak in DRC, Dr Berkley confirmed that Gavi does not currently support a stockpile for Ebola vaccines as the vaccine is currently unlicensed. Therefore, Merck currently produces and keeps the investigational vaccine and makes it available for compassionate use, as required. Dr Berkley confirmed that based on current modelling, Gavi believes there are sufficient vaccines available, and that SAGE has been asked for their advice on using the Ebola vaccine on health workers.

3. 2016-2020 Strategy: Progress, Challenges and Risks

- 3.1 Anuradha Gupta, Deputy CEO provided an update on Gavi's performance against its 2016-2020 strategic goals, including progress, challenges and risks (Doc 03).
- 3.2 Ms Gupta highlighted that Gavi was on track to achieve all its mission indicators by 2020, but that performance against the strategic indicators was more mixed with some persisting challenges.
- 3.3 Ms Gupta provided an update on the progress on key indicators under each strategic goal, as well as highlighting some of the top risks faced by the Alliance in achieving these goals. In particular, she highlighted that the risks facing the Alliance continue to evolve and that the updated Risk & Assurance report has been provided to the PPC for feedback. Ms Gupta noted that the risk of frequent and/or unplanned campaigns impacting routine immunisations is increasing, and will be further discussed as part of the Alliance Update (Doc 05b).
- 3.4 Ms Gupta noted that although progress on aggregate DTP3 coverage for Gavi countries has been made, coverage is still lower in fragile countries and some countries have seen downward revisions (e.g. Nigeria and Ethiopia) or decreasing coverage (e.g. Kenya). In addition, MCV1 coverage remains a challenge, with coverage in PEF Tier 1 and 2 countries actually decreasing.
- 3.5 She noted that Gavi has various levers in order to support countries to strengthen health systems and improve equitable coverage of vaccines. These primarily include health system strengthening (HSS) grants and PEF targeted country assessments (TCA), as well as private sector partnerships, innovation, collaboration and political will for advocacy. Ms Gupta confirmed that Gavi's HSS grants are now being focused on key coverage and equity challenges, and PEF TCA is being aligned with HSS objectives and focused on country-level support.
- 3.6 Ms Gupta emphasised the importance of having tailored and targeted approaches to address coverage and equity related challenges in each country, as well as aligning Alliance support to focus on these key challenges. She presented examples from DRC to illustrate this point, and highlighted that even in high coverage countries (such as Kyrgyzstan), risks of vaccine hesitancy and misinformation can threaten progress.
- 3.7 She highlighted that the level of countries' co-financing and self-financing for vaccine programmes continues to increase. This is an example of Gavi's successful model in mobilising domestic resources for immunisation. Ms Gupta further noted that focus was required on countries' programmatic sustainability, as well as financial sustainability, to make sure that countries continued to maintain and improve coverage levels.
- 3.8 She noted that targets for three strategic indicators are being presented for recommendation by the PPC to the Board for approval. If approved, this would mean that all strategic indicators now have targets for 2020 to enable progress to be appropriately tracked for remainder of the strategic period.

Discussion

- PPC members supported the new approach to providing a holistic update on Gavi's performance, covering progress, challenges and risks as well as Gavi's different support mechanisms.
- In response to a query from a PPC member, Ms Gupta confirmed that Gavi seeks to differentiate its support to countries based on the specific country context. As part of the Gavi 5.0 process, initial thinking has been carried out on ways to better categorise countries, and this also takes into account existing mechanisms for segmenting countries such as WHO's four tier for the AFRO region.
- PPC members raised questions on what more could be done to ensure progress in addressing equity challenges. Ms Gupta noted that the Equity Reference Group (ERG) had identified that geographic equity is generally the largest equity challenge in most countries, and therefore the entry point to tackling equity issues. The ERG has recognised three key settings for addressing equity challenges: remote/rural, urban slums and conflict, with gender-related barriers as a cross-cutting issue. Gavi is focusing on addressing these through its support with greater focus on lower coverage areas, specific urban immunisation strategies, and flexibilities provided to address issues in countries facing fragility.
- PPC members strongly supported the continued alignment of HSS grants and PEF TCA to focus on coverage and equity challenges, and emphasised the importance of exploring ways to operate in fragile settings and further progress Gavi's coverage and equity agenda.
- PPC members noted the work by Acasus on leadership, management and coordination (LMC) in DRC and the impressive progress made. Ms Gupta confirmed that Acasus is currently engaged in four countries, and confirmed that Gavi will ensure that lessons learnt from these engagements are shared with other countries, where relevant.
- PPC members supported the focus on programmatic sustainability, as well as financial sustainability. One PPC member highlighted the issue of Bolivia's coverage back-sliding, and Ms Gupta noted that a coverage survey will be undertaken in the near future which should provide further information on whether this is a data issue.
- PPC members noted the increasing risk of vaccine hesitancy in Gavi countries, and discussed the recent issues seen in India and Indonesia relating to the measles-rubella campaigns. Ms Gupta noted that the Alliance is progressing work on demand creation as a strategic focus area in order to address this risk.
- In response to a query from a PPC member, Ms Gupta confirmed that co-financing for the Cold Chain Equipment Optimisation Platform (CCEOP) is currently predominantly covered by countries' HSS grants or other Alliance partners (such as World Bank). Therefore, this is a focus area for the Alliance as well as making

sure that CCEOP is aligned with HSS objectives, and allowing the immunisation programme to reach additional areas/populations that are not currently reached.

- PPC members noted the increase in the time to cash disbursement despite the work being undertaken by the Alliance to reduce this. Ms Gupta confirmed that despite the increase, countries are using existing balances and reprogramming unspent funds to avoid disruptions to programmes. She noted that the Alliance will continue to work to bring the time down, but highlighted that there will always be outliers due to country-specific situations.
- Ms Gupta and Hope Johnson, Director, Monitoring & Evaluation, acknowledged the concerns raised by the representative of the CSO constituency in relation to the proposed target and calculation methodology for indicator S2.5-Civil Society Engagement. It was agreed that the methodology would be updated to include all Gavi-eligible countries in the denominator (not just those that had a Programme Capacity Assessment (PCA) completed), but that countries without a PCA would receive a score of zero in the calculation. Based on this understanding, the CSO constituency representative confirmed support for the proposed target, while highlighting that the CSO constituency would continue to work on developing further quantitative metrics to measure CSO engagement and a formalised reporting framework.
- PPC members confirmed they were comfortable with the proposed targets for the three strategic indicators.

Decision One

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

Approve targets for 2020 for three 2016-2020 Strategy Indicators: S2.1-Effective Vaccine Management, S2.5-Civil Society Engagement, S3.4-Institutional Capacity as set out in Section 2 of Annex A to Doc 03.

Dure Samin Akram (CSOs) recused herself and did not vote on Decision One above.

6a. Vaccine Investment Strategy

6a.1 Wilson Mok, Head of Policy, presented the final investment cases for the six shortlisted vaccines for endemic disease prevention as the third and final phase of the Vaccine Investment Strategy (VIS) 2018 (Doc 06a).

6a.2 He recalled the 2018 VIS timeline and process, and in the context of questions which had arisen recently in relation to the timing of the decision relative to the development of the future Gavi strategy, he indicated that as with the previous two cycles for the VIS, the rationale behind the timing of the VIS is that it serves as the evidence-based process whereby the highest priority vaccines are identified. This

then provides key input into the strategy development. He also indicated that there are some near-term implications in the recommendation proposed for consideration, which if delayed, could negatively impact some ongoing programmes and market-shaping activities.

- 6a.3 Dr Mok highlighted the key steps in the assessment of vaccines for endemic disease prevention and provided information in relation to the evaluation of candidate vaccines which had been conducted consultatively with technical partners and in-country stakeholders.
- 6a.4 He indicated how the VIS candidates expand the reach of immunisation and support integration of health programmes and outlined how they would enable Gavi's portfolio to further evolve towards greater country choice.
- 6a.5 Dr Mok outlined the investment cases for each of the six candidate vaccines and presented information in relation to the health impact and value for money compared across the six candidates. He demonstrated how the learning agenda for the VIS candidates would optimise programme design and enhance impact, and finally presented the financial implications of the proposed recommendation.

Discussion

- PPC members expressed appreciation for the high-quality work undertaken by all involved in the VIS process to date, with particular acknowledgement of the Secretariat team and the VIS Steering Committee (SC).
- PPC members discussed the diversity among the six candidate vaccines – some of which support existing WHO recommendations and some of which will be new to market. PPC members acknowledged that some of the vaccine candidates are different to those in Gavi's existing portfolio, whether because they are regionally-specific or are targeted to different age groups (e.g. birth, 2nd year of life, school entry, adolescence, pregnancy) thereby contributing to strengthening the 'lifecourse' approach within EPI. PPC members discussed the challenges that some of these differences may present for the Secretariat, Alliance partners, and Gavi-eligible countries in operationalising these programmes.
- Several PPC members commented on the wide applicability of the VIS process, and the implications for broader priority-setting. One PPC member noted how important this VIS work was beyond Gavi-eligible countries and that it should be shared. He also suggested that as more vaccines are taken up in immunisation programmes, it becomes increasingly important that SAGE discuss the most optimal schedule for delivery of vaccines. Another member urged the immunisation community to continue to move towards shared priorities and alignment across strategic plans (e.g. Global Vaccine Action Plan 2.0).
- PPC members tended to agree that Board-level discussion and agreement on broad parameters for the strategic direction for 2021-2025 would help inform a decision for these vaccines. In particular, the Committee suggested that the Board would discuss questions around 1) Gavi's role in moving towards a lifecourse

approach to vaccination to support Primary Health Care (PHC) and achieve Universal Health Care (UHC), and 2) Gavi's approach to wider programmes for comprehensive disease control and prevention, such as water, sanitation, animal control, vis-à-vis other stakeholders.

- At the same time, PPC members indicated broad support for the learning agenda and its associated financial implications.
- One PPC member reminded the Committee about Gavi's purpose of making vaccines available in Gavi-eligible countries as soon as they are available in high income countries, without delay.
- The PPC members representing the vaccine manufacturer constituencies cautioned the PPC about the importance of sending early and strong signals of intent to potential manufacturers to avoid delay in delivery and to Gavi-eligible countries for planning purposes.
- Following discussion, PPC members agreed to move forward with two recommendations: a short-term recommendation to prevent disruption to the cholera programme, and a longer-term recommendation conditional on June 2019 Board discussion on the 2021-2015 strategy.

Decision Two

The Gavi Alliance Programme and Policy Committee **recommended** to the Gavi Alliance Board that it, subject to the availability of funding for the 2021-2025 period following Gavi's replenishment for that period and subject to alignment with the final parameter setting for Gavi 5.0 at the June 2019 Board meeting:

- a) **Approve** support for diphtheria, tetanus & pertussis-containing (D, T & P) vaccines (tetanus-diphtheria, diphtheria-tetanus-whole-cell-pertussis, pentavalent) to be used as booster doses beginning in 2021 by:
 - i. Providing funding to establish platforms as catalytic support for the introduction of each D, T, & P-containing vaccine as a booster dose;
 - ii. Supporting the procurement of above mentioned D, T, & P-containing booster vaccines in line with the co-financing policy.
- b) **Approve** support for hepatitis B birth dose beginning in 2021 by:
 - i. Providing funding to establish platforms as catalytic support for the introduction of hepatitis B vaccine administered at birth
 - ii. Supporting the procurement of hepatitis B vaccines in standard vial presentations and in line with the co-financing policy.
- c) **Approve**, in principle, an expansion of the existing meningococcal programme to support a targeted approach that includes, in principle, support for ACW-containing

multivalent meningococcal conjugate vaccines, 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 multivalent meningococcal vaccine investment case set out in Doc 06a Annex C.

- d) **Approve** a transition of the oral cholera vaccine programme to include a preventive immunisation programme with vaccine co-financing, beginning in 2021.
- e) **Approve** support for human rabies vaccine for post-exposure prophylaxis, beginning in 2021.
- f) **Approve:**
 - i. In principle, support for Respiratory Syncytial Virus (RSV) immunisation products, 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 RSV investment case set out in Doc 06a Annex C.
 - ii. Support beginning in 2019 for pre-introduction activities for RSV immunisation products including evidence and demand generation.
- g) **Approve** the VIS learning agenda for 2019-2025 for D, T & P-containing booster vaccines, hepatitis B birth dose, ACW-containing multivalent meningococcal conjugate vaccines and human rabies vaccine for post-exposure prophylaxis, as described in Doc 06a Section 5.
- h) **Note** that the financial implications associated with the above conditional approvals for 2019-2020 are expected to be approximately US\$ 6.5 million, comprised of approximately US\$ 3 million in 2019 (which the Secretariat will strive to absorb from the Board-approved PEF budget for that year) and US\$ 3.5 million in 2020 for the VIS learning agenda for the vaccines described above and RSV introduction planning activities.
- i) **Note** the financial implications associated with the above approvals (taken as a whole) for 2021-2025 for vaccine and operational cost support are expected to be approximately US\$ 373 million, comprised of approximately US\$ 360 million for vaccine and operational cost support and approximately US\$ 13 million for the VIS learning agenda and RSV introduction planning activities.

Decision Three

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

- a) **Approve** an extension of Gavi support for use of the global cholera stockpile in endemic settings for 2020, whereby components of the preventive immunisation programme are implemented beginning in 2019.

- b) **Authorise** the Secretariat, under the Programme Funding Policy, to (i) allot funding to the global cholera stockpile based on a financial forecast endorsed by the Board, (ii) allot funding to extend budgets to future years and/or (iii) adjust annual budget amounts as authorised by the CEO/DCEO taking into account updated timing of implementation and budget utilisation;
- c) **Approve** the VIS learning agenda activities for cholera for 2019-2025 as described in Doc 06a Section 5; and
- d) **Note** that the financial implications associated with the above approvals for 2019-2020 are expected to be approximately US\$ 43.5 million, comprised of approximately US\$ 0.5 million in 2019 (which the Secretariat will strive to absorb from the Board-approved Partners' Engagement Framework (PEF) budget for that year) and US\$ 1 million in 2020 for the VIS learning agenda for cholera, and US\$ 42 million for extension of cholera support in 2020.

Adar Poonawalla (DCVMN) and An Vermeersch (IFPMA) recused themselves and did not vote on Decisions Two and Three above.

6b. Gavi's Support for Inactivated Poliovirus Vaccine (IPV) post 2020

- 6b.1 Seth Berkley, CEO, introduced this item, recalling that at its June 2018 meeting the Board had acknowledged that while IPV would be included as part of the VIS process, it would not follow the same criteria as other vaccines. He also recalled that the Board had emphasised the importance of balancing risk and cost, including opportunity costs and how IPV might be managed vis-a-vis other Gavi investments. He concluded by indicating that it is becoming increasingly clear that funding for IPV, should Gavi continue to play a role in this going forward, should be outside of Gavi's standard replenishment asks and not substitutional to Gavi's core mandate.
- 6b.2 Michel Zaffran, Director, Global Polio Eradication Initiative (GPEI), acknowledged the successful partnership between Gavi and GPEI and outlined the new strategy for polio eradication for 2019-2023. He explained that this strategy will have three pillars; eradication, certification, and integration and synergies and will overlap with the action plan on transition, which was recently approved by the World Health Assembly (WHA).
- 6b.3 Stephen Sosler, Technical Advisor, Vaccine Implementation, recalled Gavi's engagement with IPV to date (Doc 06b). He presented the outcomes of recent consultations with stakeholders around IPV, noting that there is a very low risk appetite for IPV discontinuation and that the Hexavalent vaccine was considered an important option and countries would welcome this introduction. The consultations also revealed that Gavi's role in market shaping should increase in the near term and that Gavi should consider exploring alternative funding mechanisms.

- 6b.4 Dr Sosler outlined Gavi's approach to the development of risk-based options for continued engagement with IPV and demonstrated that when the risks for the Gavi 5.0 period were assessed, it was noted that the majority of high-risk countries for polio re-emergence tended to be low income countries in the initial self-financing stage of Gavi funding and those at lowest risk are already in transition from Gavi funding.
- 6b.5 Dr Sosler outlined the range of investment options for IPV, noting that full support was the highest cost option to Gavi. A risk-based option was therefore generated as a middle ground between high risk and high cost.
- 6b.6 Dr Sosler described the consideration of supporting a hexavalent vaccine in terms of programmatic advantages, risks and the proposed support options. The estimated procurement costs were then outlined for standalone IPV and then including the switch to Hexavalent for three options: Gavi providing full IPV support; risk-based IPV support; and following standard Gavi policies.

Discussion

- Committee members recognised the importance of supporting the polio eradication initiative and the key role that Gavi should play in this. There was also acknowledgement that long term support is required beyond the strategic period 2021-2025.
- There was significant discussion regarding the funding options. Some constituencies supported the risk-based approach (Option 2) and raised concerns around Gavi funding the entirety (Option 1).
- Whilst recognising the increased costs for Gavi, the constituencies in support of full Gavi funding were not comfortable in putting the risk of failure onto the countries and specifically recognised low-income countries who may not be able to fund this over such a long timescale. There was also recognition that polio should be treated differently to other diseases due to the global public good nature of the eradication initiative and long-term commitment required.
- There was some discussion around the merits of delaying the Board decision on this area until June 2019 which some members felt would enable better alignment with the Gavi 5.0 strategy. However, after discussion, the majority agreed that there is a need for rapid movement on this key topic and that there was unlikely to be any additional information in six months which would materially change the decision.
- The PPC representative from India requested that there should be a recognition that India, though self-financing the vaccines, may need exceptional support if there are unforeseen exigencies. Given current uncertainties around the Polio endgame, she requested that a provision be made for the Board to consider such support in the future, should the need arise.

- In response to questions around whether the funding is for a full or fractional doses of IPV, the Secretariat confirmed that current funding could be for either, and that it was a matter of country choice whether full or fractional doses were used.
- Some members were supportive of the idea of using a delineated funding stream for IPV, such as IFFIm.
- In response to concerns over delayed certification, the Secretariat acknowledged the risk of delayed timelines but highlighted that all partners are working together towards the same timescales and therefore any 'plan B' would need to be discussed together.
- Committee members were generally supportive of the opportunities around the hexavalent vaccine and agreed that Gavi was an appropriate vehicle to work in this space, taking into account its market shaping activities. It was indicated that support to hexavalent vaccine will be subject to a set of conditions including supply of IPV stand-alone and DTP-containing vaccines not being compromised or impacted by this support.
- Majority positions (positions in favour of Option 1 – Full support for IPV) were expressed by PPC members representing the Bill & Melinda Gates Foundation, Civil Society Organisations, UNICEF, the World Bank and the EMRO constituency. The Board member from the UK/Qatar constituency, attending this meeting as an observer, also indicated his constituencies' preference for Option 1. Minority positions (positions in favour of Option 2 – Cost-sharing support for IPV) were expressed by PPC members representing the Norway/Netherlands/Sweden and Germany/France/Luxembourg/EC/Ireland constituencies. The Board member from the US/Australia/Japan/Korea (Rep. of) constituency, also attending this meeting as an observer, indicated her constituencies' preference for Option 2.

Decision Four

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

- a) **Approve**, subject to the availability of funding for the 2021-2025 period following Gavi's replenishment for that period, support for inactivated poliovirus vaccine (IPV) under the arrangements agreed by the Board in November 2013 (Option 1 in paragraphs 3.3);
- b) **Approve**, in-principle support for IPV containing whole-cell pertussis Hexavalent vaccine (Hexavalent) for the administration of IPV, diphtheria, tetanus, whole-cell pertussis, hepatitis B and Haemophilus influenza b antigens, subject to a vaccine being licenced, recommended for use by WHO, WHO pre-qualified and that market attributes support the successful implementation of Hexavalent;
- c) **Note** that the financial implications associated with these decisions are expected to be approximately US\$ 850 million (of which an estimated US\$ 848 million is dedicated to standalone IPV) for the period 2021-2025 and that, given that financing

for IPV was not included in the investment case for the replenishment in 2015, funds for IPV support beyond 2020 should be considered as additional to other Gavi investments.

Adar Poonawalla (DCVMN) and An Vermeersch (IFPMA) recused themselves and did not vote on Decision Four above.

10. IFFIm and CEPI

- 10.1 Lene Lothe, Norway, provided background on the Coalition for Epidemic Preparedness Innovations (CEPI) programme and explained Norway's preference of using IFFIm (International Finance Facility for Immunisation) as an existing infrastructure to frontload Norway's financial contribution to CEPI.
- 10.2 She recognised the extra burden of this project on the Secretariat and reassured the Committee of Norway's wish to conduct the arrangement in as efficient a manner as possible. She highlighted the complimentary benefits of this transaction to the involved parties of CEPI, Gavi and IFFIm working towards a shared goal.
- 10.3 Ms Lothe explained that the Audit and Finance Committee (AFC) had discussed the potential impact of this programme at its meeting the previous week and had confirmed that it would not have any adverse impact on Gavi's finances or operations. However the AFC had also provided guidance that the arrangement should remain cost neutral to the Secretariat, that the legal agreement framework should remain the same and that the Secretariat should put in place appropriate programme management structures.
- 10.4 Ms Lothe also noted that the IFFIm Board had discussed the proposal at its meeting earlier this week and was very supportive of the proposed arrangement. She highlighted their guidance in relation to ensuring there is an appropriate bond market to support the bond issuance and ensuring that the transaction does not have any material adverse impact on IFFIm's ability to access the capital markets efficiently (e.g. due to a negative pricing signal).

Discussion

- The Committee was generally supportive of this arrangement as long as neither Gavi's mandate nor IFFIm's structure were altered. The World Bank confirmed that this would not impact IFFIm's existing structure. Some members recognised the merit in Gavi and CEPI working together towards a shared strategy by developing new vaccines.
- PPC members noted that the UK, who had previously raised concerns about this proposal, confirmed that their concerns had now been addressed and they were in support of the proposal.
- The PPC member from France raised some concerns that funding of research and development (R&D) is out of Gavi's mandate, particularly if this opens the door to

other R&D programmes. He also raised concerns about the lack of oversight on CEPI and whilst it was recognised that this constitutes a relatively small amount of funds they would prefer other mechanisms to be explored.

5a. Review of Strategic partnership with India

- 5a.1 Hind Khatib-Othman, Managing Director Country Programmes, introduced this item recalling that India is a very important country in Gavi's portfolio in that it contributes to 30% of Gavi's coverage performance and 15-20% of Gavi's impact goals, and that India is not only advancing the country's immunisation programme but also lifting the performance of Gavi's global agenda. She referred to the request from India for support for IPV, based on special circumstances which the country has encountered.
- 5a.2 Carol Szeto, Senior Country Manager, presented progress on the Board-approved Gavi strategic partnership with India for 2016-2021 (Doc 05a) highlighting the strong progress made with respect to the four objectives of the partnership, namely (i) coverage and equity; (ii) new vaccines introduction; (iii) market shaping; and (iv) sustainable transition.
- 5a.3 She noted in particular that Gavi's HSS support has contributed to a steady increase in immunisation coverage by strengthening the health system; that Gavi's support has catalysed vaccine introductions as planned; that the partnership has been catalytic in unlocking domestic resources for immunisation and that there is exceptionally strong political commitment to immunisation by the Indian government. She also noted that the partnership is expected to result in significant procurement savings for Gavi-supported countries while it has already enhanced global supply security for pentavalent vaccine.
- 5a.4 Ms Szeto also outlined several risks that could affect the partnership's success going forward, including the country's management capacity given the significant immunisation programme expansion, anti-vaccine lobbies and vaccine hesitations, political risks in light of upcoming general elections, and transition risks with delayed new vaccines expansion given competing budget priorities and vaccine security.
- 5a.5 Ms Szeto provided information relating to India's request to Gavi for support for IPV for three years which would amount to US\$ 40 million for Gavi. She outlined the background to this request, as well as three options for the PPC's consideration, namely (i) Gavi not to fund the cost-sharing proposal; (ii) Gavi to partially fund the proposal; or (iii) Gavi to fund the proposal as request for three years from 2019 to 2021.
- 5a.6 Vandana Gurnani, Joint Secretary of Reproductive and Child Health from the Government of India, and also a PPC member, thanked Gavi for the successful partnership. She reiterated India's strong high-level political and financial commitment to immunisation, and commented on the significant achievements made through Mission Indradhanush in raising coverage in low-performing areas.

She further underlined India's strong commitment to further expand and build its immunisation programme, building on Gavi's catalytic support.

- 5a.7 She provided information to the PPC in relation to India's investments toward polio to date, recalling that while India had initially been reluctant to introduce IPV given vaccine security concerns, it had finally agreed to self-finance IPV as a global public good, after being assured by the global community of the continued availability of the vaccine. The request from India to Gavi is in the context of significant price increases for the vaccine as a result of a market adjustment as subsidies to a manufacturer have come to an end, and queries from the Minister of Finance relating to the consideration for IPV versus other priority vaccines, given cost-effectiveness. The Government of India faces a trade-off decision between continuing IPV, which poses a high risk to the IPV programme in India and the global polio eradication agenda, and expanding new vaccines.
- 5a.8 Ms Gurnani requested the PPC also to consider, in terms of equity, that India had initially been one of the few Gavi-eligible countries excluded from Gavi's IPV support and that a decision in India's favour would be consistent with Gavi's overall low risk appetite towards IPV.

Discussion

- PPC members congratulated India and Gavi on the tremendous success of the partnership. They further commended India for the outstanding political commitment to immunisation, and the successes achieved in its immunisation programme.
- Given India's outstanding political commitment and the successes achieved, in addition to Gavi's overall low risk appetite towards polio eradication, the potentially unacceptably high risk to the polio endgame agenda given the endemic nature of the region, the risk to Gavi's partnership with India, and equity considerations about providing IPV support to all other Gavi eligible countries versus meeting India's cost-sharing funding request, a majority of PPC members supported the proposal to fully cost-share the cost of IPV for three years.
- Some PPC members were concerned about the policy implication of setting a precedent if Gavi was to fund the cost-share proposal, in that Gavi might be asked to step in at other times when countries are faced with a price increase of a vaccine they were already self-financing. One PPC member noted that if a precedent was set, any exception to Gavi's policy should be applied in an equitable manner to all Gavi countries. Some PPC members therefore instead encouraged Gavi to look into alternative ways to support India, including market shaping interventions or cost-saving potentials within the already approved US\$ 500 million support to India within this period.
- In response to the questions on whether other solutions had been discussed at all, e.g. that India uses part of the already-approved Gavi funding for the partnership to mitigate the fiscal impact caused by the price increase of IPV, the Secretariat clarified that the US\$ 500 million earmarked for the partnership had been designed

for specific purposes (four new vaccines and HSS) and that most had already been committed/expensed. There is remaining funding allocated for HPV, but this vaccine is also very important to India as well as to Gavi.

- Several PPC members asked to better understand the reason for the IPV price increase and that Gavi worked towards ensuring sustainable pricing in the long term. In response, it was clarified that one of the drivers for the previous price agreement on IPV had been a time-bound agreement for 2014-2018 to facilitate the IPV uptake. With a limited number of manufacturers, there was a need to work towards more sustainable solutions.
- In order to clarify some of the concerns around setting a precedent, the Secretariat noted that the 2013 Board decision on IPV had clearly stated that any request from India related to IPV would be considered by the Board.
- Minority positions were expressed by PPC members representing the Norway/Netherlands/Sweden and Germany/France/Luxembourg/EC/Ireland constituencies. The PPC member from the CSO constituency indicated that she would abstain from the decision-making process due to conflicting views within her constituency.

Decision Five

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

Approve, further to its decision on exceptional Gavi support for IPV from 2013 for Gavi eligible and graduating countries and the risks to the polio eradication agenda, the use of core resources (in an amount estimated at US\$ 40 million based on current projections) to support inactivated poliovirus vaccine (IPV) in India for the period 2019-2021.

Vandana Gurnani (India), Adar Poonawalla (DCVMN) and An Vermeersch (IFPMA) recused themselves and did not vote on Decision Five.

5b. Alliance Update

- 5b.1 Hind Khatib-Othman, Managing Director, Country Programmes, provided key country, programmatic and policy updates to the PPC (Doc 05b).
- 5b.2 She highlighted ongoing and planned Alliance support for Syria, in the context of a recommendation being put forward to the PPC for consideration. She reported on countries' appetite to introduce Typhoid conjugate vaccine (TCV) following the approval of support for TCV by the Gavi Board in November 2017. She noted the need for stronger technical guidance to countries around TCV proposal development and implementation and that the Secretariat would continue to gather lessons learned on the implementation of the programme and impact of the vaccine.

- 5b.3 Ms Khatib-Othman also provided an update on the implementation of the Fragility, Emergencies, Refugees Policy. She informed the PPC of the various requests for flexibilities approved under the policy to date and of the need to adjust Gavi's normal procedures to handle urgent, time-sensitive requests. She noted that several initial lessons could be drawn from the first year of implementation of the policy, including that countries did not regularly include co-financing for refugees in their planning, driving partners (particularly UNICEF) to co-finance for refugee doses. Going forward, Gavi would review the need for potential policy adjustments.
- 5b.4 Ms Khatib-Othman provided an update on the HSIS and PBF reviews, noting that these reviews, as relevant, would inform the next HSIS policy review, which is expected to start in 2019 in preparation for the next strategic period.
- 5b.5 Robin Nandy, the PPC member representing UNICEF, and Devi Aung, Senior Programme Manager, Vaccine Implementation, provided an update on balancing incentives for Gavi-supported measles and rubella immunisation activities. Dr Nandy noted that while MCV1 coverage had stagnated in Gavi countries, MCV2 coverage had shown some progress. Nevertheless, the quality and coverage of measles campaigns needs to be improved, with only two countries achieving the target of 95% coverage. Dr Nandy acknowledged the important role campaigns play in the control of vaccine preventable diseases, yet that it was important to avoid an over reliance on campaigns.
- 5b.6 Dr Nandy outlined some of the concerns raised by the Independent Review Committee (IRC) in July 2018, including continued reliance on nationwide campaigns that may not be reaching the unreached and continued missed opportunities to strengthen RI services. He informed PPC members that the IRC had requested Gavi to consider allowing countries flexibilities in their operational costs that would allow them to target areas with high numbers of zero and one dose children.
- 5b.7 He further presented two examples of countries: one with frequent campaigns including outbreak responses (DRC) and one with high routine measles coverage, with subnational heterogeneity of coverage, requiring tailored and targeted approaches (Ghana). While DRC, despite frequent Supplementary Immunisation Activities (SIAs), saw continuing measles outbreaks, Ghana, with high MCV1 and increasing MVC2 coverage required less frequent (every 4-5 years) campaigns, and yet, there are areas where routine coverage is lower than national average, which could potentially be considered for tailored approaches within the country.
- 5b.8 Dr Aung explained that on a bigger picture Gavi was planning to take a comprehensive approach to the issues raised and to address them at several levels, including through Gavi's polices and application guidelines, better planning and monitoring of campaigns and a push for improved global normative guidance.
- 5b.9 To respond to PPC and IRC concerns, and recognising that Gavi's current incentive structure for campaigns, particularly for M/MR follow-up campaigns, may inadvertently promote nationwide SIAs, Dr Aung presented a decision point to the PPC to recommend to the Board to approve flexibilities for countries applying for follow-up M/MR SIAs to request up to the full amount of operational costs based

on the nationwide target population to conduct immunisation activities that are tailored to the country's epidemiologic situation targeted at reaching zero dose and one dose children through nationwide, subnational and/or enhanced intensification of routine immunisation.

- 5b.10 Dr Aung pointed out that, if approved, Gavi proposed to work with partners to implement the new approach in a number of countries and to collect relevant learnings. Regular programme updates would be presented to the PPC.
- 5b.11 Nadia Lasri, Senior Country Manager, presented an update on the development of an accountability framework in the context of the June 2018 Board decision to provide exceptional support to Nigeria. She recalled the principles of Nigeria, as agreed by the Board, noting that work on developing the accountability framework had only started once all outstanding amounts of misused funds had been fully reimbursed.
- 5b.12 Ms Lasri explained that the current draft accountability framework contains five clusters of indicators, one of which includes non-negotiable requirements for continuous Gavi support. Any non-compliance with the requirements specified in this cluster, in particular around fiduciary accountability and co-financing, would imply an immediate suspension of all Gavi cash and new vaccine support until the identified issues were rectified. Ms Lasri presented several draft indicators pertaining to the further four clusters, health financing, programmatic performance, governance and financial management and institutional capacity. In addition to the potential for an immediate suspension of all Gavi cash and new vaccine support, Ms Lasri informed the PPC of further possible implications that could be triggered by the results of the accountability framework.
- 5b.13 Ms Lasri presented illustrative examples of a performance rating mechanism, that was to be defined for each indicator, and which would be aggregated into a Heatmap, to be reviewed annually. She noted that in addition to the accountability framework, specific requirements would be negotiated with each focus state and that Gavi's Grant Performance Framework would be applied to monitor Gavi-specific support. Ms Lasri concluded by presenting the next steps that would be undertaken to finalise the accountability framework.

Discussion

- PPC members unanimously confirmed their support to the proposed recommendation in relation to Syria, asking the Secretariat to ensure that it engages with all humanitarian and development partners and stakeholders in the development of a proposal for support and in the implementation of support. PPC members also emphasised that Gavi ensures support is equitably accessible across the whole country.
- One PPC member noted that for TCV there are three large implementation trials ongoing in Bangladesh, Malawi and Nepal and suggested that the Secretariat should include the learnings from these trials to see how the vaccine is used in reality, along with the implementation from Pakistan.

- With respect to the update on the implementation of the Fragility, Emergencies, Refugees Policy, one PPC member noted the need to review the policy with respect to the question of partner co-financing for refugee populations. The member noted that the principle of co-financing is aimed at encouraging sustainability in government, however when asking Alliance partners to co-finance it could drain limited resources that could be spent elsewhere. The Secretariat clarified that this issue had been discussed by the Board prior to the approval of the policy and that, while this aspect of the policy would be reviewed, joint advocacy from all Alliance partners would be needed to encourage government co-financing of vaccines for refugee populations. The PPC member from the CSO constituency noted challenges for CSOs in coordinating with the government in the request for, and implementation of, policy flexibilities and lack of awareness of many CSOs of the policy. She recommended that the policy, going forward, should be implemented in a more pro-active manner.
- With respect to the update on balancing incentives for Gavi-supported measles and rubella immunisation activities PPC members acknowledged that, while campaigns remain an important instrument to ensuring outbreak response and herd immunity, current Gavi support structures should be clearly aligned to the goals of strengthening routine immunisation, achieving high immunity, and avoiding over-reliance on campaigns. PPC members further acknowledged the challenges associated with providing resources for Human Resource costs, and advised that Gavi be more prescriptive in which Human Resource costs it supported.
- While voicing overall support for the recommendation to provide more flexibilities to countries, PPC members noted that it was important to be specific and consistent in terms of the guidance provided and proposed that the use of these flexibilities was tested in a few priority countries. Gavi, through the Alliance coordination team, should carefully monitor the implementation of the flexibilities in these countries and report back on progress.
- PPC members further acknowledged the need for coherence in guidance across SAGE, RITAGs, the Measles-Rubella Initiative (MRI) and technical working groups and agreed that it was important that SAGE provided clear guidance on the frequency and implementation of SIAs and that the MRI and technical working groups revisit the relevant incentive structures and provide guidance on how to improve the quality of SIAs and/or on how to ensure routine immunisation is strengthened. Alliance partner regional offices would need to ensure appropriate implementation at the regional and national levels.
- One PPC member further noted that it was important to ensure alignment among Alliance members with respect to WHA decisions around Measles elimination goals, and that it was important that countries be empowered to take decisions most suitable to their needs and contexts, including around innovative ways of improving coverage. She further cautioned against overburdening countries with undertaking detailed data analysis, as capacity at country level was limited. In response, the Secretariat stressed the critical role Alliance partner offices play in formulating high quality proposals.

- In response to a request from one PPC member to amend the language of the recommendation, the Secretariat clarified that the language was designed to allow countries greater flexibilities in how they use Gavi support to develop country specific strategies to reach zero or one dose children and improve routine immunisation.
- With respect to the development of an accountability framework in Nigeria, PPC members commended the Secretariat for the work undertaken to date. They further emphasised the importance of clearly defining which accountability framework indicators were absolutely non-negotiable requirements for continuous Gavi support and, if not complied with, would lead to an immediate suspension of all Gavi cash and new vaccine support. PPC members advised not to use programmatic indicators, such as an indicator around coverage, as a non-negotiable indicator but to limit this category of indicators to financial misuse and financial commitments. It was further noted that the World Bank would play a critical role in verifying the financial and health financing indicators.
- PPC members suggested that some Gavi Board members join the annual in-country review process of the accountability framework as this would allow for greater scrutiny and, if needed, pressure on the country to keep its commitments. The Secretariat clarified that Gavi's High Level Review Panel was mandated to formally review and extend the programme, and will be supplemented by a high level in-country review led by the CEO/DCEO to ensure sustained political commitment at the highest levels.
- PPC members noted the importance of ensuring strong national ownership of the accountability framework as well as alignment with other ongoing primary health care initiatives.
- They also emphasised the importance of a strong alignment among donors and stakeholders in country, including between the Global Fund, GFF, WB, BMGF and Gavi.
- One PPC member noted that given the upcoming elections Gavi should mainly focus on the federal level, as opposed to working at the state level, and asked to explore how to ensure better linkages with the polio task force's work on Routine Immunisation in Nigeria. It was further noted that Gavi should be vigilant with respect to expenditures on the government endorsed "Community Health Influencers Promoters and Services" programme.

Decision Six

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

Approve extending 2017/2018 support for Syria approved by the Gavi Alliance Board in December 2016 for use in 2019.

Decision Seven

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

Approve the following wording to be included as Annex B to Gavi's HSIS support framework

Annex B –Operational Cost Support for Measles Containing Vaccines

In order to encourage countries to strengthen routine immunisation for measles containing vaccines (MCV) and reach zero and one dose children, countries are able to apply for operational costs support for M/MR follow-up supplementary immunisation activities (SIAs) up to the national 9-59 month population, to be used for national SIAs, subnational SIAs and enhanced routine immunisation activities targeted at reaching missed children.

6c Pandemic Influenza Preparedness

- 6c.1 Wilson Mok, Head, Policy presented this item to the PPC, recalling that the Gavi Board had requested a detailed briefing on pandemic influenza at its June 2018 meeting (Doc 06c).
- 6c.2. Dr Mok noted that this follows the Board approval for the evaluation framework for vaccines for epidemic preparedness and response which was agreed as part of the wider Vaccine Investment Strategy (VIS) discussion earlier in the year, and explained that pandemic influenza vaccine is the only vaccine which is currently at the appropriate stage in this framework for discussion of potential investment.
- 6c.3 Dr Mok described the characteristics of pandemic influenza and emphasised the higher risk to low income countries. He highlighted the significant efforts by partners, specifically WHO, to strengthen pandemic influenza preparedness. However, he noted that despite these efforts, challenges remain in relation to both vaccine supply and demand.
- 6c.4 Dr Mok highlighted supply challenges and noted that one option which had been considered was to providing funding to secure unclaimed current capacity and to increase manufacturing capacity but that stakeholders were not supportive of this due to the high costs and risks. A second supply option would be to help accelerate development of new technology, but stakeholders did not recommend that Gavi provide a market signal via a financial commitment at this point.
- 6c.6 Regarding demand challenges, Dr Mok explained that these include limited country capacity to accept vaccines and limited capacity to deliver to priority groups and priority populations being unwilling or unable to receive the vaccines.

6c.7 Dr Mok outlined a proposal for Gavi to support a learning agenda to assess the feasibility and impact of routine immunisation of healthcare workers with seasonal influenza vaccines to improve pandemic readiness.

Discussion

- Committee members were generally supportive of the proposal for a learning agenda in relation to health care workers and influenza. Members agreed that having a system in place before a pandemic would better enable preparedness. There was also acknowledgement from members that this proposal is different to the VIS learning agenda, because this is not a commitment for Gavi to take on a new routine immunisation programme and it should not be considered an automatic invite for broader investment by Gavi.
- Committee members also agreed with the proposals not to take forward options which the Secretariat had previously explored but had been ruled out by discussing with stakeholders, i.e. reserving additional production capacity for pandemic influenza vaccine or providing a market signal for new technologies via a financial commitment.
- The Committee recognised the challenges with routine immunisation for health care workers including previous experience of reticence of health care workers to accept vaccinations. Members agreed that effective communication would be an essential part of this agenda as well as ensuring equity across the entire health care workforce so that benefits are assessed for all.
- It was also recognised that this learning agenda could provide interesting outcomes which could apply to other diseases for which healthcare worker vaccination is relevant, such as Ebola or hepatitis B. Members also raised the importance of distinguishing between challenges of immunising in pandemic and seasonal settings.
- One member raised concerns about how this proposal fits into the wider plan of other organisations working in these areas such as WHO and UNICEF. Whilst there was reassurance from both the Secretariat and WHO that this plan was developed collaboratively and is designed to be complementary and would not duplicate work by others, it was suggested that it would be useful to have clarity on the division of responsibilities between different organisations.

Decision Eight

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

- a) **Approve** the development of a learning agenda to assess the feasibility and impact of routine influenza immunisation of healthcare workers to support epidemic and pandemic influenza preparedness;

- b) **Note** the financial implications associated with the above approval for 2019-2022 are expected to be approximately US\$ 4 million, comprised of approximately US\$ 1 million in 2019 (which the Secretariat will strive to absorb from the Board-approved Partners' Engagement Framework (PEF) budget for that year), US\$ 1 million in 2020 and US\$ 2 million in 2021-2022.

Princess Nothema Simelela (WHO) recused herself and did not vote on Decision Eight.

7. Gavi Support for Yellow Fever Diagnostic Capacity

- 7.1. Lee Hampton, Senior Specialist, Monitoring & Evaluation, and Sylvie Briand, Director, Infectious Hazardous Management Department, WHO, presented this item to the PPC (Doc 07) recalling the discussion at the May 2018 meeting of the Committee and the subsequent work carried out between the Secretariat and WHO, the Eliminating Yellow Fever Epidemics (EYE) Laboratory Technical Working Group (LTWG) and other stakeholders to inform the proposal which is being put to the PPC at this meeting for consideration.
- 7.2 Dr Briand highlighted that diagnostic capacity is essential for the EYE project as yellow fever symptoms can be confused with other diseases and this creates difficulty in identifying yellow fever outbreaks as well as immunity gaps in the population. She reminded the Committee that emergency stockpiles cannot be deployed without laboratory confirmation.
- 7.3 Dr Briand presented a case study of a yellow fever outbreak in Nigeria in 2017-2018 where the lack of laboratory capacity was a significant challenge. She then explained laboratory strengths and challenges seen in Africa and outlined potential solutions to the challenges.
- 7.4 Dr Hampton noted that manufacturers have indicated interest in working with Gavi on making validated tests commercially available if support was provided. He noted that ensuring sufficient funding to support yellow fever diagnostic testing is available in the long-term from non-Gavi sources, particularly from national governments, would be an important part of the proposal and that national governments were often already covering important elements, such as laboratory staff salaries.

Discussion

- PPC members recognised the importance of this issue not just for Africa but also with regards to the potential transmission of a yellow fever outbreak outside of Africa, and were generally supportive of the proposal.
- Some PPC members saw this as an opportunity to improve regional and national laboratory capacity and generate sustainable improvements in health systems which could have positive impacts for other diseases. It was however

acknowledged that as it is a new project the results are uncertain and it will need to be closely monitored.

- In response to questions from the PPC, the Secretariat confirmed that the proposed efforts would not duplicate the efforts of other organisations but were instead designed to be complementary. The Secretariat also confirmed that they were eager for co-financing support to begin as early as possible with countries and to build this into the national budgets, although this may take some time.
- In response to concerns raised by a member on the amount of funding proposed for encouraging the commercial availability of diagnostic tests, the Secretariat clarified that they believe that the funding is sufficient based on discussions with potential manufacturers.
- Concerns were raised during discussions about whether this recommendation constitutes a shift in Gavi's mandate towards diagnostics and market shaping which have not been officially approved by the Board. The Secretariat sought to assuage fears on 'opening the door' to market shaping, explaining that the yellow fever diagnostic market is relatively unusual in that there is very little demand for yellow fever diagnostics in upper income countries since yellow fever is not found in those countries. For other vaccine preventable diseases, such as measles, validated tests are generally commercially available because of demand for those tests in upper income countries.
- It was proposed that Gavi could generate a bigger impact by focussing on routine immunisation or contribute to more a holistic approach rather than disease by disease approach for laboratory support alongside WHO and other partners, although other members acknowledged the benefits of being able to test for and confirm cases of specific diseases as well as a learning agenda in yellow fever and that this could help to inform future WHO and partner work.
- Minority positions were expressed by PPC members representing the Germany/France/Luxembourg/EC/Ireland and CSO constituencies.

Decision Nine

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

- a) **Approve** an amount of up to US\$ 8.2 million during 2019-2021 (of which US\$ 4.6 million would be for 2019-2020) for costs related to the procurement and distribution of laboratory reagents, supplies, and equipment for yellow fever diagnostic capacity strengthening through a diagnostic procurement mechanism based on Gavi's existing application, review, and approval processes;
- b) **Note** the expected use of Partners' Engagement Framework (PEF) funds, estimated at approximately US\$ 5.3 million during 2019-2021, to support yellow fever diagnostic capacity strengthening; including technical assistance, quality assurance/quality control assessments, support for sample transportation, and coordination. The Gavi

Secretariat will seek to absorb the 2019 estimated costs of US\$ 1.7 million within existing approved budgets;

- c) **Note** the continued limited use of health systems strengthening (HSS) funds to support surveillance and laboratory capacity in the context of national plans that focus on achieving and maintaining high immunisation coverage and address underlying equity challenges; and
- d) **Request** the Gavi Secretariat to report back to the PPC and Board on progress in 2019.

Kate O'Brien (R&THI) recused herself and did not vote on Decision Nine.

8. Engagement with countries post-transition: Country plans for Angola, Congo Republic, Timor Leste

- 8.1 Santiago Cornejo, Director, Immunisation, Financing and Sustainability, presented the item (Doc 08) to the PPC, recalling the June 2018 Board decision requesting robust individual country plans for Angola, Congo Republic and Timor-Leste to be presented to the PPC. He noted that such plans have now been developed for each of these countries with action plans and associated costs.
- 8.2 Mr Cornejo presented detailed information in relation to the post-transition plans for Angola and Timor-Leste. With regard to Congo Republic, he described the significant decline in Gross National Income (GNI) per capita which decreased by over 50% between 2014 and 2017 to US\$ 1,360. While Congo Republic's three-year GNI per capita average¹ remains just above Gavi's eligibility threshold of US\$ 1,580, the latest GNI is significantly lower and represents the largest decrease among Gavi countries. He further noted that while the IMF projects economic growth in Congo Republic for 2018, this growth would not be enough to prevent the country from regaining Gavi eligibility in 2020. Mr Cornejo therefore presented a proposal that Congo Republic be considered Gavi-eligible again from 1 January 2019 on the basis that the original idea behind the three year GNI average did not take into account the possibility of countries economically deteriorating after transitioning out of Gavi support.
- 8.7 Mr Cornejo concluded by outlining the request for an additional US\$ 10 million support for Angola and Timor-Leste, explaining that Congo Republic were to be considered Gavi-eligible, it would be supported through Gavi's regular budget and funding windows.

Discussion

- PPC members recognised the significant work undertaken by the Secretariat in partnership with the countries to create these new detailed plans, and confirmed

¹ Gavi's Eligibility and Transition Policy states countries are Gavi-eligible if their average GNI p.c. over the past three years is equal to or below the threshold amount.

their support for the recommendations relating to Angola and Timor Leste, recognising the importance of building country capacity and planning for both financial and programmatic sustainability.

- While PPC members were also generally supportive of the proposal to consider the Congo Republic as Gavi-eligible, some concerns were raised about this being perceived as a possible shift in Gavi's policy. Committee members recognised the exceptional situation relating to Congo's economic status and becoming re-eligible for funding. The Secretariat assured Committee members that they will closely monitor the other countries which are transitioning out of Gavi support and raise any concerns to the Board.
- Several members agreed with the proposal not to fund vaccines which had previously received Gavi support in Congo. However, other members raised concerns of the ability of Congo Republic to continue funding these vaccines in light of the poor economic outlook and that this may create an inconsistent policy with regards to other currently eligible countries. Several members encouraged the Secretariat to consider a 'Plan B' in case the Congo Republic is no longer able to fund their existing vaccine programmes.
- The Committee discussed the exception of the Gavi policy to use an average of three years of GNI data to determine eligibility. In the context of the discussion, the Secretariat acknowledged the potential utility of exploring additional data points for determining eligibility in the next Gavi period.
- One member acknowledged that training epidemiologists and health workers in their own language is a good theory but cautioned the Secretariat to bear in mind the risk of these health workers then leaving the country to then explore opportunities elsewhere. Another member raised the suggestion of using accountability frameworks similar to that recently developed for Nigeria.

Decision Ten

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

- a) **Approve**, exceptionally, that the determination of Congo Republic's eligibility for 2019 will be based on the latest GNI data instead of the average GNI per capita over the past three years and to increase the HSS envelope to up to US\$ 10 million for a five year period;
- b) **Request** the Secretariat to monitor the provision of domestic financing for vaccines in Congo Republic and report back to the Programme and Policy Committee and Board should challenges arise; and
- c) **Approve** within the overall Partners Engagement Framework an additional amount of up to US\$ 10 million for post-transition support for Angola and Timor-Leste for the period 2018-2023, bringing the total approved post-transition support to these countries up to US\$ 30 million.

11. Gavi 5.0: The Alliance's 2021-2025 Strategy

- 11.1 Seth Berkley, CEO, provided an overview of the initial thinking for Gavi 5.0, and presented some key questions where Committee members' guidance and advice was sought to steer the development of the Alliance's 2021-2025 strategy (Doc 11). Dr Berkley noted that a radical change in Gavi's strategy and focus is not proposed for Gavi 5.0, but rather an update to take into account the move from Millennium Development Goals (MDGs) to Sustainable Development Goals (SDGs), and the changes in the broader landscape. He confirmed that it is proposed that Gavi will continue to focus on its core mandate of supporting countries to introduce vaccines and achieve equitable coverage of their immunisation programmes.
- 11.2 Dr Berkley noted that as countries transition out of Gavi support, the mix of countries remaining Gavi-eligible will be diverse and that Gavi will need to think about how countries are categorised to allow for differentiated approaches to address specific country challenges.
- 11.3 Dr Berkley referenced work done by Hans Rosling focusing on the world's most vulnerable people, rather than on the poorest nations, and which shows that the most vulnerable people are now living in lower-middle-income countries (LMIC) rather than lower-income countries (LICs), which is an important consideration when thinking about Gavi 5.0. He highlighted that some middle-income countries (MICs) that have never received Gavi support are lagging behind in terms of their immunisation programme performance, and these countries face individual, specific challenges.
- 11.4 Dr Berkley highlighted that the risk of disease outbreaks continues to increase and that Gavi is currently a key contributor in supporting outbreak detection, prevention and response. He noted that there is an opportunity for Gavi's support to be more systematic in this space and further aligned with other organisations.
- 11.5 Dr Berkley noted that immunisation provides a touchpoint for the basic package of primary healthcare (PHC) interventions, and PHC in turn provides a platform for universal healthcare (UHC). He therefore highlighted the importance of immunisation as a building block for the health system and a platform for countries to leverage to achieve UHC.
- 11.6 Dr Berkley reiterated that this is initial thinking on potential directions for Gavi 5.0 and therefore further analysis is required. He confirmed that the next steps will be to present these considerations to the Board for discussion in November, followed by individual consultations with Board members, and then a dedicated discussion at the Board retreat in March 2019.

Discussion

- PPC members noted their support for the initial thinking on Gavi 5.0 and the strategic questions presented to frame the discussion. Committee members highlighted the importance of taking into account the larger macro trends for Gavi, particularly the demographic and political trends.

- PPC members emphasised the importance of staying focused on Gavi's core mandate of improving coverage and equity – or 'equitable coverage'.
- Dr Ngozi Okonjo-Iweala, Gavi Board Chair, emphasised the importance of ensuring that the PPC and Board provide clear guidance to the Secretariat and contribute to helping the Secretariat come up with a strategy for the 2021-2025 period within a wider vision for the future. She highlighted that in order to do this, it would be important to think more long-term and have an idea of what Gavi 6.0, 7.0, etc. might look like in order to inform Gavi 5.0.
- Dr Ngozi highlighted the importance of thinking carefully about the medium-term and the current global tensions, including the reduced appetite by some countries to continue maintaining aid budgets. She emphasised that it will be important to understand the mind-sets of policy makers and consider how Gavi will respond to these uncertainties. Dr Ngozi highlighted that the idea of health and immunisation as a global public good is critical, and that it will be important to focus on Gavi's comparative strengths (such as bringing things to scale, which allows it to do market shaping and innovative financing).
- PPC members highlighted that Gavi can bring focus and attention to areas even if they are not financing them, and that it will be important to continue to use the Alliance's voice to highlight issues.
- PPC members noted the importance of considering how Gavi interacts with non-Gavi eligible countries and MICs. Committee members noted that financing is not generally the problem in these countries and that how Gavi might interact with these countries would need to be further considered, including support for pricing negotiations and provision of technical assistance. In this context, some PPC members noted that significant changes to Gavi's eligibility policies for Gavi 5.0 were not currently anticipated.
- Dr Berkley agreed with comments from PPC members related to ensuring that planned programmatic and policy evaluations are scheduled so as to inform Gavi 5.0, in so far as is possible, and that a clear theory of change is articulated for the next strategic period. Further to this, a PPC member highlighted the idea of defining what a mature vaccine programme looks like so there is a clear vision and goal for countries.
- Dr Ngozi and various PPC members noted that the multilateral system is currently not delivering to its full potential in terms of strengthening health systems. It is therefore imperative that Gavi look at how it works across the health sector and development space, and see how this can be improved. Dr Ngozi noted the importance of being clear on how Gavi works with other organisations, and how Gavi 5.0 aligns with GVAP 2.0, the WHO investment case, etc. Dr Berkley noted that it is important for Gavi to be humble in this space as there is currently no perfect model, and noted that Gavi will continue to work with other organisations to see how to accelerate progress on HSS and how this progress can be better measured. Dr Berkley further noted the importance of collaboration and emphasised that the Alliance has expanded dramatically in terms of the number

of partners, so it will be important to be focused in terms of how, when, and with whom, we are collaborating.

- Dr Ngozi noted that up to now Gavi has made great progress, but that the problems left to address are potentially the most difficult ones. Therefore, Dr Ngozi highlighted that we may need to think differently about how we approach these problems in order to make progress.

12. Review of decisions

- 12.1 Joanne Goetz, Head, Governance, reviewed the decision language with the Committee which was approved by them.
- 12.2 Committee members noted that VIS, IPV including India, Pandemic Influenza and Yellow Fever would be standalone items for the November 2018 Board meeting and that all other PPC recommendations would be presented to the Board on its consent agenda.

9. Approaches to Fiduciary Risk Management in Gavi's Cash Grants

- 9.1 Jacob van der Blij, Head, Risk and Hind Khatib-Othman, Managing Director, Country Programmes, provided an update on how Gavi approaches fiduciary risk management in Gavi's cash grants (Doc 11). They noted that while using country systems is critical for Gavi's model, doing so comes with an increased risk of misuse for which the Board had set a low risk appetite.
- 9.2 Ms Khatib-Othman presented a portfolio analysis of the current situation, outlined potential solutions to in relation to strengthening Gavi's assurance model and leveraging countries' own capacity as well as exploring alternative fiduciary risk mitigation models that provide more embedded fiduciary monitoring and assurance, potentially ensure more targeted capacity-building, are tailored to countries' context and risk profiles and are complementary to the programmatic role of core partners.
- 9.4 Ms Khatib-Othman noted that a formal evaluation of the scale up of alternative models would take place in 2019 and 2020 in a representative sample of countries. She further explained that a significant change to the partner-government funding portfolio split was only expected post 2020, given the lead time and available resources necessary to do so, and that doing so was projected to reduce the ratio of funds to partners to ~60% by 2020 and to ~50% by 2025.

Discussion

- PPC members thanked the Secretariat for the analyses undertaken and the options presented, and confirmed overall support for the proposal to explore

alternative fiduciary risk management models, noting that it was important to use country systems as much as possible.

- Several PPC members also noted a desire to further accelerate the timelines around moving funding back through government systems and expressed the hope that initial results might already be available earlier than the end of 2019.
- Several PPC members clarified that their fiduciary risk appetite remained low and that this low risk appetite would need to be taken into consideration when exploring alternative fiduciary risk management models.
- One PPC member further stated that to build in-country capacities and systems it was not always necessary to move funding through government systems and asked that the Secretariat, through a clearly defined theory of change, identifies the tools that are most conducive and appropriate to achieving the aims of channelling more funds through government systems and building country systems, while keeping fiduciary risks at a low level.
- Several PPC member noted that channelling funding through non Alliance partners, including through pooled funding mechanisms, might have implications for ensuring adequate accountability for the use of funds, while noting several promising examples of the use of such pooled funding mechanisms. In response, the Secretariat clarified that funding that went into pooled funding mechanisms was generally subject to the same performance indicators as other funds and that similar reporting and governance standards applied.
- Several PPC members expressed a desire to better understand how much of the funding that is channelled through partners is immediately passed back to government systems as this would shift the government partner portfolio funding split.
- The PPC member representing the World Bank referred to a study from the World Bank on the cost of parallel fiduciary arrangements, and noted that, according to the study, the costs of using parallel arrangements were four times higher than those of using country systems, while often not adequately minimising fiduciary risks. The PPC member agreed to share the study with all PPC members.
- One PPC member suggested that the partner sustainability group could help to look at the analysis and asked how the Secretariat could be more pro-active in terms of not only identifying patterns of fiduciary risk related issues but also be more proactively in addressing them.
- In response to questions by several PPC members the Secretariat explained that it was in some areas collaborating with the Global Fund to mitigate fiduciary risks and build in-country capacity, but that, given differences in the business models of the organisations, such collaboration remains limited. PPC members noted that feedback from countries indicate that the Global Fund is often perceived as setting up parallel systems.

- It was suggested that it might be useful for the PPC to have a year by year view on the % of funding being channelled away from governments, as well as an analysis of the areas of funding that are most prone to fiduciary risk as well as criteria that determine the use of the different options. It was also indicated that it would be useful to have a better understanding of how the options link with Gavi's established risk management processes, such as the Programme Capacity Assessments.
- In response to a question the Secretariat explained that it worked with local partners in providing fiduciary risk assurances and building capacities where feasible, relevant and practical.
- Dr Ngozi Okonjo-Iweala, Gavi Board Chair, responding to a comment from one PPC member, reminded the PPC of the previous Board and PPC discussions on this topic and on the request by several Board members to reverse the trend of channelling funds away from governments. She also noted the need for a strong dialogue and collaboration with Ministers of Finance to achieve the dual goal of moving more funding back through government systems and maintaining acceptable fiduciary risk levels. The Secretariat confirmed that Gavi is focusing on leveraging countries' own systems and ensuring that funds are 'on budget', as well as building the capacity of the national oversight mechanisms.
- The Secretariat noted that it would continue to clarify and strengthen its budget guidance to countries, including around Human Resources related operational costs to reduce the potential for misuse of funds. It was also noted that questions around the adequate management of fiduciary risks would be addressed when developing Gavi's next strategy, with a commitment to improving public financial management in countries as a long term goal.

13. Any other business

- 13.1 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

- Richard Sezibera, Chair (Day One)
- Kate O'Brien (Chair, Day Two)
- Ahmed Abdallah
- Dure Samin Akram
- Edna Yolani Batres
- Abdul Wali Ghayur
- Vandana Gurnani
- Lene Lothe
- Violaine Mitchell
- Robin Nandy
- Jean-François Pactet
- Adar Poonawalla
- Helen Rees (By phone)
- Michael Kent Ranson
- Princess Nothema Simelela
- An Vermeersch
- Seth Berkley, Chief Executive Officer
- Alejandro Cravioto

Regrets

- Jason Lane

Other Board members attending

- Danny Graymore, UK/Qatar
- Irene Koek, US/Australia/Japan/South Korea

Guests

- Sylvie Briand WHO (Item 7)
- Michel Zaffran, WHO (Item 6b)

Observers

- Stephen Karengera, Special Adviser to the PPC Chair
- Fabienne N'Guessan Kombo, Special Adviser to the AFRO Francophone/Lusophone constituency
- Sara Osman, Special Adviser to the EMRO constituency
- Rolando Pinel, Special Adviser to the EURO/PAHO constituency
- Bruno Rivalan, Special Adviser to the CSO constituency
- Khant Soe, Special Adviser to the SEARO/WPRO constituency

Gavi Secretariat

- Anuradha Gupta
- Johannes Ahrendts (Agenda Items 2, 3, 9, 11)
- Pascal Bijleveld
- Mirjam Clados
- Santiago Cornejo
- Anne Cronin (Agenda Items 3, 6a, 8)
- Sally Dalgaard
- Alex de Jonquières
- Marthe Sylvie Essengue Elouma (Agenda Items 2, 3, 5b, 6b, 8)
- Joanne Goetz
- Quentin Guillon (Agenda Items 3, 11)
- Lee Hampton (Agenda Item 7)
- Hope Johnson
- Marius Keller (Agenda Item 3)
- Hind Khatib-Othman
- Ranjana Kumar (Agenda Items 2, 3, 5b)
- Simon Lamb (Agenda Item 9)
- Nadia Lasri (Agenda Item 5b)
- Wilson Mok (Agenda Items 2, 3, 5b, 6a, 6b, 6c, 11)
- Aurélia Nguyen
- David Powell (Agenda Items 2, 3, 5b, 9)
- Marie-Ange Saraka-Yao
- Antara Sinha
- Colette Selman (Agenda Items 2, 3, 5b, 6b, 8)
- Stephen Sosler (Agenda Items 6b)
- Eelco Szabo
- Michael Thomas
- Jacob van der Blij
- Charlie Whetham (Agenda Items 2, 3, 5a, 5b, 6b, 8)
- Carol Szeto (Agenda Item 5a)