

## **Gavi Alliance Programme and Policy Committee Meeting**

26-27 October 2017

Gavi Alliance Offices, Geneva, Switzerland

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

- 1.1 Finding a quorum of members present, the meeting commenced at 09.00 Geneva time on 26 October 2017. Richard Sezibera, Programme and Policy Committee (PPC) Chair, chaired the meeting.
- 1.2 The Chair welcomed participants and in particular the new PPC member, Adar Poonawalla.
- 1.3 The Chair noted that An Vermeersch was joining this meeting as an observer, pending her formal appointment by the Board as a PPC member to represent the IFPMA constituency. She would not be taking part in the discussions as Lindsey Dietschi continued to formally represent the constituency until the end of the year.
- 1.4 The Chair informed participants that he had exceptionally agreed, at the request of Gavi's Australian Board member, to allow Sue Graves to observe the meeting on his behalf. He had also agreed at the request of Jean-Marie Okwo-Bele, who would be retiring shortly from his position at WHO, to enable Diana Chang Blanc to accompany him to this meeting as an observer.
- 1.5 Finally, he indicated that Bernhard Schwärtlander and Michel Zaffran from WHO would join for the session on Polio Transition Planning, along with Mike McGovern, Chair of the Rotary International Polio Plus Committee and Chair of the GPEI Transition Management Group (TMG).
- 1.6 Standing declarations of interest were tabled to the Committee (Doc 01a in the Committee pack).
- 1.7 The minutes of the 11-12 May 2017 meeting were tabled to the Committee for information (Doc 01b in the Committee pack). The minutes had been circulated and approved by no-objection on 28 July 2017. He also referred to a recommendation which had been approved by the PPC by unanimous consent on 2 June 2017 (Doc 01c in the Committee pack).
- 1.8 The Chair referred to the PPC workplan (Doc 01d) and the Action Sheet (Doc 01e). He reminded Committee members that they may contribute to the workplan by raising issues with either himself or the Secretariat. He noted that

the workplan sets out the prospective agenda and dates for future meetings and is an important part of PPC meeting and agenda planning.

- 1.9 Finally, the Chair referred to the survey, completed by PPC members on *BoardEffect* after the meeting in May. It had not been possible to do a proper analysis of the results as only four of the ten respondents had submitted a complete survey. He encouraged members to complete the survey which they would receive after this meeting, as it is a useful source of information to ensure continuous improvement in the preparations for the PPC meetings.

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## **2. CEO Update and Update on Implementation of Gavi's Strategy**

- 2.1 Seth Berkley, CEO, commenced his presentation by indicating how honoured he was to have been reappointed by the Board to continue his mandate as CEO.
- 2.2 He referred to the joint session which had taken place with the Evaluation Advisory Committee the previous day and reiterated his strong belief in the importance of measurement and learning, and evaluations as a part of that, as Gavi moves forward.
- 2.3 He then addressed some key developments in the global landscape, referring in particular to the work done so far by the new Director General of WHO, who has presented his new leadership team, as well as a bold work plan, with Universal Health Coverage (UHC) as a central part of his agenda.
- 2.4 He recalled the heavy engagement of the Secretariat and the Bill & Melinda Gates Foundation (BMGF) in working to ensure that SAGE consider a more appropriate indicator for immunisation and was pleased that SAGE was now recommending an indicator taking into account coverage with DTP, MR, PCV and HPV.
- 2.5 He referred to a number of changes that had taken place at the political levels in Gavi donor countries over the past few months, as well as a number of significant changes in the leadership in the vaccine industry since the last replenishment. He expressed his satisfaction, in particular in the context of the current political climate globally, that donors maintain their support of Gavi. He referred to Gavi's mid-term review (MTR) which will take place in 2018 and which will be a critical milestone to demonstrate that Gavi is delivering on its strategy.
- 2.6 He provided an update in relation to progress on work in Syria and India. He reported on the increasing number of cholera outbreaks during recent months, with Gavi support being provided through the cholera stockpile for campaigns in Nigeria, Sierra Leone and Bangladesh.
- 2.7 He confirmed that the Gavi Secretariat has been give formal observer status on the International Coordinating Group (ICG) on vaccine provision. An evaluation of the ICG has now been completed and the report is being finalised.

- 2.8 He provided information to the PPC on some new partnerships in innovation with the private sector, and that the 2018-2019 budget which is being recommended by the Audit and Finance Committee (AFC) to the Board for approval includes an increased budget line for such partnerships.
- 2.9 The CEO then gave an update on the implementation of Gavi's strategy (Doc 02). He referred to the need to amend some part of the indicator framework, in particular in terms of reporting intervals and definitions as the current list does not allow to measure real-time evolutions.
- 2.10 He presented information in relation to the mission indicators which are on track and indicators focussing on breadth of protection (on track), routine immunisation coverage and equity (off track); effective vaccine management (off track); and institutional capacity (slight improvement, no target).
- 2.11 He highlighted that co-financing performance has significantly improved since 2014 and is now at a record high.
- 2.12 He reported that the strong momentum in the new HPV strategy is at risk due to supply issues.
- 2.13 He concluded his report by presenting information on the Alliance Key Performance Indicators which track the efficiency and effectiveness of Gavi mechanisms.
- 2.14 Finally, he presented information on the investment decision framework and the forecast of resources to meet expenditure in 2016-2020, as reviewed and approved by the Audit and Finance Committee at its meeting the previous week.

### *Discussion*

- PPC members were pleased to note that the Gavi Secretariat had been granted observer status on the ICG. They also noted that the evaluation of the ICG mechanism had been completed and that at a subsequent meeting of a high-level group a set of recommendations had been agreed on which included the setting up of an oversight committee for the whole ICG mechanism. In the meantime Gavi would continue to be observer of the ICG emergency operational decision making process.
- PPC members welcomed the update on progress on Strategy, Mission and Alliance indicators, expressing concerns in particular in relation to those pertaining to coverage and equity and health system strengthening. One PPC member suggested that there should be a discussion on holding countries and partners accountable for delivery rather than changing the indicators and/or data.
- In response to a query from a PPC member the Secretariat noted that the proposed changes referred to reporting timelines as well as the ability to measure changes in real time as opposed to revising the ambition and later shared with the PPC information outlining the governance processes which were in place in relation to approval, ownership and monitoring of the Strategy,

Mission and Alliance indicators. One PPC member stated his view that Board approved indicators include approval of reporting processes and that any proposals to change the frequency of reporting should subsequently be discussed and approved by the Board.

- PPC members noted that Gavi was currently not on track to meet its coverage and equity targets and expressed concerns in relation to the health systems strengthening indicators although it was also noted that it was early in the reporting period and many changes have been implemented and may take time to deliver results. It was noted that Gavi support could only be catalytic and that Gavi's support and results attributed to Gavi's investment must be considered in the context of the overall weaknesses of primary health care services and health systems in any given country.
- In response to a question from a PPC member, the Secretariat noted that in many countries private sector coverage may not be captured in administrative data, but it should be covered in survey data, so if survey data shows higher coverage rates then that may be an indication of private sector engagement.
- Some PPC members suggested that Gavi should look at the immunisation situation in non Gavi-eligible countries, in particular in middle income countries who were never Gavi-eligible, to ascertain how they are performing relative to Gavi countries, keeping in mind that many of these countries are also supported by Alliance Partners through other mechanisms.
- It was suggested in relation to market-shaping that it might be good to consider risks around potential 'over' shaping for some vaccines. The Secretariat noted that it will indeed be important to keep an eye on this as for some vaccines the market is now very mature with a large number of suppliers and it will be necessary to ensure that market shaping activities consider this while continuing to work on shaping markets for other vaccines.
- PPC members agreed that subnational approaches are critical, ensuring management capacity at the subnational level and getting subnational data. PPC members noted that a lot of work is being done by CSOs on demand creation at the subnational level.
- The PPC member represented the CSO constituency shared the constituency view that the CSOs are partners who are not being utilised to full capacity and that further work could be done to look at the CSO platforms in countries and benefit from the work they are doing in particular in relation to demand generation, service delivery and research. The CEO acknowledged the contributions of CSOs in countries and highlighted the importance of them being considered a part of the core programme in countries as are other Alliance Partners. He recalled that Gavi's core mechanism to engage CSOs is through country-level dialogues between governments, CSO platforms, other core partners and SCMs.

- It was suggested that it might be useful for the Board at its upcoming meeting to have a quick review of how work is progressing with Syria, what lessons have been learned so far and some of the issues that may have to be addressed going forward.
- It was also suggested that it would be useful for the PPC to receive more detailed information on the private sector partnerships that Gavi is developing to have a better understanding of what is being funded, what the strategies are and how they related to improving coverage and equity and country plans. The CEO suggested that this be included for the next meeting of the PPC.
- PPC members noted that while discussions on data often focus on the availability and quality of data that there is a need to have more conversations on the culture of the use of data in particular so that countries, not only at national but also at subnational level, understand the importance of accurate data reporting to inform decisions to help them to improve coverage, equity and systems.
- PPC members appointed pointed out the importance of Gavi's engagement on political will. The CEO confirmed that a lot of work is done on political advocacy throughout the Alliance and noted that it would be useful for the PPC to have a discussion on how it might be possible to do this work more systematically going forward.

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### **3. Partner's Engagement Framework**

- 3.1 Anuradha Gupta, Deputy CEO, presented an update to the PPC on the Partners' Engagement Framework (PEF) (Doc 03), highlighting some of the learnings that are coming out of implementation of the PEF model since it was launched in 2016.
- 3.2 She outlined that there is continuous progress on the key principles of the PEF namely country focus, differentiation, transparency and accountability. These are driving a country-driven approach with greater clarity on roles and responsibilities of the different stakeholders.
- 3.3 She reported that the PEF resources are progressively shifting to the country-level and that there is a request for an increase in the budget in 2018 and 2019 which would go for additional targeted country assistance (TCA). She presented information on the allocation of resources to countries in Tiers 1, 2 and 3, highlighting that there are now fragile countries in Tier 3 who would need additional support.
- 3.4 Ms Gupta highlighted the importance of providing technical assistance (TA) in countries at a subnational level as this is where there are more prominent and systemic resources gaps.

- 3.5 In relation to supply chain, she indicated that findings are showing that this is an area where countries need more embedded support. She reported that under the guidance of the PEF management team, special investments in supply chain are being rebalanced at the global and regional levels, and that there is a great emphasis being put on effective stock management.
- 3.6 She reported that there is still a lot of work to be done on data quality requirements (DQR) compliance, and that to date PEF investments in data have been heavily concentrated at the global and regional levels and that there needs to be a shift toward investments at the country level. This is why new directions are being set with data strategic focus area (SFA) investments with relevant foundational support being repurposed. Disaggregation and triangulation are the key focus and at the recent SAGE meeting, subnational estimates were presented for the first time.
- 3.7 Ms Gupta referred to the work being done on leadership, management and coordination (LMC) and financial management, where expanded partners play a key role.
- 3.8 She emphasised that partners are at the heart of the Alliance and in this context referred to the Alliance Health Survey which had raised issues around trust, coordination and communication among WHO, UNICEF and the Secretariat and which will be addressed going forward. She looked forward to the World Bank and CDC being part of the next health survey. She indicated that in the spirit of nurturing the Alliance, an Alliance directory is being prepared for the first time and that Alliance-wide 'brown bag' sessions are being organised.
- 3.9 Finally, she highlighted the future directions for the PEF: focus on results; segmentation of countries with an intentional approach to TA; bolster EPI leadership in reviewing plans and performance; increased mobilisation of location institutions; continuing to improve Alliance health.

### *Discussion*

- PPC members agreed on the usefulness of data triangulation and highlighted that in large countries such as Nigeria that this is critical not only at the national level but also at the subnational level and that this is something which should be explored further, also in relation to stock management, including distribution.
- PPC members noted the important of ensuring that the capacity strengthening at the country level is for the Ministry of Health and not for partners as the desire is to ensure sustainability for the countries themselves. One PPC member pointed out that in many countries the issue firstly relates to capacity filling before there can be any capacity building.
- Some PPC members noted that because partners manage a large portion of the HSS grants, it is not always clear how the support to countries and partners is differentiated between the PEF and HSS and that it would be useful going forward to have a broader perspective on how the different funding streams are channelled, including through partners. It was clarified by the Secretariat that

PEF focuses on TA by partners whereas channelling of HSIS via partners is included under the CP update. It was agreed that it would be useful for the PPC to have more detail in relation to the expanded partners.

- One PPC member also asked for further information in relation to the percentage of the total number of staff in WHO and UNICEF working on immunisation who are Gavi funded. The UNICEF representative on the PPC estimated this to be at around 30% for UNICEF.
- In response to a comment from some PPC members the Secretariat clarified that PEF funding for staff is committed for two years, which gives the possibility of providing appropriate commitments to attract talented profiles. It was pointed out that the PEF model does not emphasise incremental budgeting, that it is performance-based funding to partners which therefore includes a semi-annual cycle of milestone reporting and performance reviews.

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#### **4. Alliance Update on Country Programmes**

- 4.1 Hind Khatib-Othman, Managing Director, Country Programmes, introduced this item (Doc 04), which would focus mainly on two issues - the role of supplementary immunisation activities (SIAs) and campaigns in the strengthening of routine immunisation, and the channelling of funds away from and back to government systems.
- 4.2 Robin Nandy, Chief of Immunizations, UNICEF, presented on the first topic, highlighting that during the 2016-2020 strategic period campaigns are expected to account for approximately 40%-50% of Gavi-supported immunisation events, compared to approximately 20% during the 2011-2015 strategic period.
- 4.3 He presented information on both the positive and negative effects of campaigns on routine immunisation efforts, giving examples from Nepal, Ethiopia, Nigeria and Cambodia. He concluded that strong routine immunisation is key to ensuring high coverage and equity, and that campaigns, wherever possible, should be used to strengthen and supplement routine immunisation. He opined that the focus needs to be on improving planning and addressing the quality of campaigns and on limiting any negative impact they might have on routine immunisation systems. He also opined that, with every campaign, two or three activities that strengthen the routine system should be envisaged, for which partners can be accountable. The type, scale and duration of campaigns needs to be adapted to each country context and linked to the risk of disease outbreaks.
- 4.4 Finally, he outlined potential approaches to ensure that campaigns are benefitting routine immunisation efforts and requested guidance from the PPC on the direction the Alliance should take to intensify these approaches.
- 4.5 Ms Khatib-Othman presented on the second topic, highlighting that the PPC and Board have expressed concerns that more and more funding is being channelled

away from government systems. She noted by the end of 2017, approximately 77% of cash could potentially be channelled away from governments, on the assumption that Gavi signs Memorandums of Understanding (that are currently under review) with partners on 34 grants and that these grants are disbursed.

- 4.6 She highlighted that the funding modality decisions are based on a pro-active, risk- and case by case review in line with the Board-approved risk appetite and that to move back to government systems a diligent assessment of countries' capacity to manage grants in line with the current Board risk appetite is needed.
- 4.7 She outlined that financial management capacity building efforts are ongoing and that further discussions are needed with partners in relation to ensuring that all Memorandums of Understanding with partners (which regulate the terms on which partners manage Gavi grants) include in-country capacity building components and performance assessments of partners when they manage Gavi grants.
- 4.8 Finally, Ms Khatib-Othman referred to a recommendation that the PPC was being asked to considered in relation to the continuation of Gavi support to South Sudan irrespective of its default status on its 2016 co-financing obligations, and confirmed that at its next meeting the PPC will be asked to consider a proposal on a proposed medium-term approach to replace reactive approvals of continuation of support for Yemen and South Sudan despite these countries' default status.

### *Discussion*

- PPC members confirmed their support for the proposed recommendation concerning South Sudan. It was suggested when this decision was communicated to the country that this might be an opportunity to encourage the country to look towards increasing its health budget or to consider how different country assets beyond those at the disposal of the health ministry might be used to contribute to strengthening the immunisation programme.
- Participants expressed their appreciation for the country summary sheets which they found to be most useful.
- PPC members welcomed the balanced analysis of the impact of campaigns on routine immunisation and indicated support for the proposed approaches to ensure that campaigns are benefitting routine immunisation systems.
- It was suggested that further work could be done to explore the possibility of running multi-antigen campaigns and PPC members asked Alliance partners to ensure that campaigns represent good value for money.
- One PPC member pointed out that the dichotomy between the terms 'routine' and 'campaigns' are now blurred as the term 'campaigns' now spans a broader spectrum of activities, including PIRIs (Periodic Intensification of Routine Immunisation) and child health days. It was suggested that WHO provide



standard nomenclature as many in the field are used to the terms routine and campaign.

- PPC members noted that from the perspective of the partners the channelling of funding through them is neither optimal nor desirable but supported by them in the interests of the Alliance. It is seen as an interim solution and there is agreement that long-term solutions need to be found so as not to undermine country ownership and sustainability of programmes in the long run. At the same time the Secretariat was asked to continue to explore opportunities for building in-country capacity to ensure sustainability of programmes even while funding was not channelled through government systems.
- Concerns were expressed in relation to the information shared that approximately 77% of cash could be channelled away from government systems by next year and it was agreed that the PPC should receive an update on this at its next meeting to monitor closely the direction in which this is going. The PPC also asked that hybrid options (whereby the higher risk elements of the programme, such as, for example, the procurement of high value goods, are channelled through Alliance partners, with lower monetary based activities remaining with the government) be further explored where possible.
- It was suggested that it would be useful if at its next meeting a proposal for additional steps that might be taken before moving funding away from government systems could be presented to the PPC. If possible the additional steps should be designed in a way to give an opportunity to governments to address the identified challenges and gaps before a final decision was made to channel funding away from government systems and/or establish a clear road map for how funding would be channelled back to governments.
- The information provided on sustainability tracers was welcomed as a positive development. In this context one PPC member asked if there will be an opportunity to build the capacity to model the total cost of immunising a child. The Secretariat added that it is not only about costing immunisation, which is indeed being looked at, but also links to the primary health systems which deliver the immunisation services.

### **Decision One**

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

**Find** that exceptional circumstances in South Sudan justify the continuation of Gavi support irrespective of its default status on its 2016 co-financing obligations.

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## **5. Polio transition planning**

- 5.1 Michel Zaffran, WHO, Director, Polio Eradication, and Diana Chang Blanc, WHO, Manager, Immunization, Vaccines and Biologicals Department presented an overview to the PPC on polio transition planning. They presented apologies from Bernhard Schwartländer, Chef de Cabinet of the Office of the Director General, who had been unable to join for the presentation due to an unforeseen competing commitment.
- 5.2 The presentation comprised an overview of the WHO corporate vision in relation to polio transition planning, of the current state of polio eradication, on the post-certification strategy, on transition planning in priority countries, and on Gavi's role in transition planning.
- 5.3 They highlighted that there is full engagement at WHO to make polio transition planning a priority of the organisation, that there is agreement that funding should not be the driver of polio transition and that it should be used as an opportunity to strengthen country capacity, support local health systems and drive progress towards Universal Health Coverage (UHC) and achieving SDG targets.
- 5.4 They presented information showing that country transition plans were behind schedule but they were committed to completing these as soon as possible so the information would be available for JA planning as well as for other partners.

### *Discussion*

- PPC members noted that based on a PPC recommendation the Board had agreed that any future investments by Gavi in IPV should be considered as part of the Vaccine Investment Strategy (VIS) which is currently being developed and that this will be on the agenda for the PPC meeting in May 2018. Some PPC members also requested a discussion on Gavi's potential role in IPV financing in 2019 and 2020 as part of the next meeting.
- Some PPC members expressed concerns that the discussions around polio transition are not as far advanced as they should perhaps be and highlighted that this is a WHO responsibility, not a GPEI responsibility. It was also pointed out that in the context of polio transition, Gavi is being considered as a donor by some countries and that not only is this unfair and unreasonable, but it goes against country ownership and Gavi processes.
- PPC members noted that in some countries GPEI-funded Surveillance Medical Officers (SMOs) are operationally integrated into the national EPI programmes. While they welcomed this they did indicate that it did not appear that there had yet been any discussions pertaining to the skill sets of the SMOs and whether or not these were transferable to new roles within the national programmes. It was suggested that it would be helpful for Gavi going forward to have more concrete information on the total numbers of polio-staff that are currently funded and what their level of effort is in non-polio surveillance. It might also be possible for Gavi to use the JAs to get more visibility on the participation of polio-funded staff in

EPI programmes. Dr Zaffran indicated that a database of all polio staff now exists and that the information can be shared after appropriate filters are applied.

- One PPC member pointed out that the discussions on staff very often focus on those hired by the partners and that there is an incredible network at the country level that also needs to be taken into consideration, such as the vaccinators who in some countries go house to house.
- Some questions were raised in relation to surveillance and who might take on this role once GPEI has been phased out.
- Questions were also raised in relation to the importance that countries themselves are putting on polio eradication using their own resources, as opposed to the emphasis which is being put on polio eradication at the global level.
- Concerns were raised in relation to fragile countries where there are so many competing priorities and it is not clear what advice is being given to the governments to enable them to make the appropriate decisions.
- Some questions were raised in relation to what might happen to endemic countries post 2021 and whether there will be a need for IPV campaigns when OPV is stopped. Dr Zaffran indicated that there may be a need for some pre-cessation campaigns to boost population immunity before stopping use of the old polio vaccine but that it is not foreseen that there will be campaigns using IPV
- PPC members noted that there are still quite a number of questions in relation to polio transition that need to be taken forward and that this will need to be a priority for WHO.

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## **6. Typhoid conjugate vaccine**

- 6.1 Seth Berkley, CEO, introduced this item by reminding PPC members that this vaccine was first prioritised in 2008 in the VIS and that it is only now that we can expect to have a prequalified vaccine by the end of the year, with five further vaccines in development. Following the recent SAGE recommendation on typhoid conjugate vaccine (TCV) use in routine immunisation as well as in catch-up campaigns, a proposal is being put forward to the PPC for consideration in relation to the opening of a funding window designed to catalyse immunisation in Gavi countries.
- 6.2 Michael Thomas, Director, Vaccine Implementation, provided a brief overview to the PPC on the proposal as outlined in Doc 06. He provided information on the global annual burden of the disease, in particular in children under five years of age and highlighted that in view of increasing cases of resistance of the disease to existing treatments that it is likely that there will be a shift in focus from treatment to prevention interventions going forward.

6.3 Mr Thomas presented some key opportunities for the Alliance if a TCV funding window was to be opened in terms of health impact, equity and market shaping. He also noted that this would be a learning opportunity for the Alliance in that it would enable a number of scientific and programmatic questions to be addressed to inform any future funding decisions.

#### *Discussion*

- The Chair shared comments which had been submitted to him in writing by Minister Umy Mwalimu on behalf of the AFRO Anglophone constituency.
- PPC members very much welcomed the proposal, noting their appreciation that vaccine manufacturers had embraced the 2008 VIS decision as a positive signal to continue their work in developing a vaccine for pre-qualification.
- Some PPC members wondered about the timing of this proposed recommendation and whether it could be rolled into the upcoming VIS discussions. It was felt that this would not be a very positive signal for the manufacturers who have continued to work on developing this vaccine based on the 2008 decision. The Secretariat also noted that it had been estimated that the opening of a funding window now could help to avert 15000 deaths over the next three years in light of constrained supply.
- PPC members did have a number of questions in relation to the appetite of countries to introduce TCV and agreed that it would be useful to have more detailed information on this as part of the post-introduction learning agenda. They highlighted the importance of any demand being country-driven with countries clearly understanding the financial implications, in particular those who are on the transition trajectory.
- It was also asked that further information be provided in advance of the Board meeting on issues related to co-administration with other vaccines.
- PPC members noted that an additional positive effect of the use of TCV is likely to be a reduction in the use of anti-malarial treatments for fever which is actually typhoid and not malaria.
- It was also noted that it will be interesting, once data becomes available, to see how the introduction of this vaccine might impact herd immunity, as this has been particularly successful with the introduction of other conjugate vaccines.
- PPC members did note that there are significant gaps in terms data on disease burden, in particular in relation to African countries, and that this will be important to monitor closely going forward.
- In response to a question from a PPC member the Secretariat clarified that India is not eligible to apply for formulaic support admissible to the rest of Gavi-supported countries. In response to some concerns raised by PPC members in relation to the market becoming very constrained should India wish to self-

procure the vaccines, the CEO noted that it is not foreseen that India would wish to introduce TCV into its programme in the coming years.

- PPC members requested that the wording of the recommendation in relation to the use of the vaccine to respond to outbreaks be modified to make it clear that it applied to Gavi-supported countries and that it also reflect the PPC discussion whereby they did not feel it appropriate to limit the use of the vaccine for outbreaks only if proven resistant to antimicrobials. PPC members also agreed to the addition of a point relating to reporting requirements to the PPC and Board.
- In response to a query from a PPC member the Secretariat clarified that Gavi would not be responsible for implementation research but that there is an active programme supported by the Bill & Melinda Gates Foundation, and that there will be further discussions with WHO to determine where there might be other ongoing research, the results of which can be used going forward to inform the learning agenda.
- It was agreed that a number of issues raised during the discussion would be clarified and included in the paper going to the Board namely in relation to i) co-administration with other vaccines, ii) timing of the decision related to TCV compared to timing associated with the VIS decision, iii) demand forecast post-introduction, iv) potential supply constraints in view of possible vaccine demand by India, v) potential risks of over-production in the long term and how this might be addressed as part of a market shaping strategy.

### **Decision Two**

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

- a) **Approve** the opening of a funding window for TCVs subject to the Secretariat receiving confirmation of WHO PQ of a vaccine such that in 2018 the Secretariat can invite country proposals for support from Gavi eligible countries.
- b) **Note** that the financial implications associated with the above approval for the period of 2019-2020 are expected to be approximately US\$ 85 million, which has been taken into account in the financial forecasts to be presented to the November 2017 Board for the 2016-2020 period.
- c) **Request** the Secretariat to develop a process to enable allocation of vaccines in Gavi-supported countries if needed in case of a typhoid outbreak and if requested by WHO.
- d) **Request** that, no later than two years from the first country introduction and in addition to regular updates, the Secretariat formally report back to the PPC and Board on lessons learned from initial country introductions and outbreak usage.

*Lindsey Dietschi (IFPMA) and Adar Poonawalla (DCVMN) recused themselves and did not vote on Decision Two above.*

## **7. Vaccine Investment Strategy: methodology**

- 7.1 Judith Kallenberg, Head, Policy, presented this item, highlighting as outlined in Doc 07, that there are two points for the PPC to consider forwarding as a recommendation to Board and three further points for guidance.
- 7.2 She indicated that Gavi's vaccine portfolio has diversified over the years to include investments beyond routine immunisation. She outlined that the VIS is an evidence-driven, consultative process to identify new vaccine opportunities and priorities, that there are diverse vaccine candidates that require differentiated evaluation approaches, and that the potential investments to accelerate access may differ in each case.

### *Discussion*

- PPC members broadly agreed that it is not Gavi's mandate to routinely fund pre-licensure vaccines for epidemic diseases, keeping in mind that the Board can always take exceptional decisions, as it did for Ebola.
- PPC members agreed that vaccines for epidemic response would need to be assessed on a case by case basis for potential Gavi support, and that this applies to CEPI as well as any other vaccine funding initiative. It will be important to ensure that the different roles and responsibilities in relation to such vaccines are clear going forward for all stakeholders.
- Participants agreed that there was likely to be a role for Gavi for IPV post-2020.
- While some also felt that it could be useful for Gavi to look at longer-term priorities, beyond the normal five-year VIS cycle, consensus was not reached on this point.
- In relation to a proposal tabled by UNICEF and WHO for Gavi to possibly consider investment in TT (tetanus toxoid) Uniject, PPC members expressed different views. Some noted the potential for tetanus elimination and impact on equity. Others questioned the value for money, noting that the use of such devices was likely to substantially increase vaccine costs and that it does not make business sense for manufacturers to invest in such devices. The Secretariat agreed to assess the potential impact and value for money of the investment. It was agreed that if there were to be further discussions on this issue it would be more appropriate for them to be outside of the VIS process.
- PPC members noted that within two to three years there may be multiple manufacturers of hexavalent vaccines and that it might be useful for Gavi to start thinking about such vaccines going forward to replace pentavalent vaccines and IPV. The Secretariat noted that this will be taken into account in the scenarios presented to the PPC on IPV in May 2018.

- PPC members agreed that Gavi can play a role in epidemic response but it was suggested that WHO should continue to take the lead in this area. In relation to the proposed approach of more regular review of potential new vaccine investments in epidemic response, the PPC asked that the Secretariat first focus on further defining evaluation criteria and indicators, in consultation with WHO and other experts. These would be considered at the next PPC meeting together with an appropriate process for investment decision-making.
- In terms of determining country interest in the different vaccines, the Secretariat noted that an initial survey focused on prioritisation criteria had included EPI managers and that further country consultations on specific vaccines would be conducted later in the process.
- In terms of how the criteria will be used to prioritise vaccines, the Secretariat noted that there has already been some input from the consultations on the relative importance of different criteria and that it will be important to strike the right balance between having a formula or equation for prioritisation and leaving room for applying judgement. Further consultations will be done in early 2018 to determine the appropriate weighting and potentially developing different options for weighting for consideration by the PPC and Board.
- PPC members noted that while there will be a link between the investment decision frameworks for endemic and epidemic vaccines they will be slightly different.
- One PPC member suggested that it would be useful to go beyond the proposed definition of financial risk protection to include recurrent costs (direct medical and non-medical costs averted as well as indirect cost associated with time lost because of illness or care averted). The Secretariat noted that this particular indicator had been discussed in depth by the VIS Steering Committee, which acknowledged that it will be important to think about what data will be available for calculating this indicator as well as the factors which would be differentiating compared to other health impact metrics.
- It was noted that for further discussions on a potential role for Gavi in relation to vaccine boosters it will be important to consider the types of investments that are suited to Gavi's mandate and comparative strengths and also to include this in a potentially wider discussion in relation to Gavi's role in 'vaccines' versus 'vaccination' which is an issue that has also arisen during the consultations.
- PPC members noted that a dialogue will be starting soon on Gavi's future strategy and that any emerging views from those discussions will be incorporated into the VIS discussions next year.

### **Decision Three**

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

- a) **Approve** the evaluation criteria for potential new investments in vaccines and other immunisation products primarily intended for endemic disease prevention; these include ranking criteria (health impact, economic impact, equity and social protection impact, global health security impact, and value for money), secondary criteria (other impact, Gavi's comparative advantage, broader health systems benefits, implementation feasibility, and alternate interventions) and cost criteria (vaccine cost, operational cost, and additional implementation costs) as further described in Table 1 and Section 4 of Doc 07;
- b) **Request** the Secretariat, in consultation with WHO and other experts, to develop evaluation criteria for potential new investments in vaccines for epidemic response for PPC review and Board approval.

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## **8. Engagement with countries post-transition**

- 8.1 Seth Berkley, CEO, introduced this item, recalling that at its retreat in April 2017 the Board had delved in-depth into the issues of transition, concluding that most countries are on track for successful transition and that the current transition policy is appropriate. The Board had asked the Secretariat to consider putting together tailored approaches for five countries who were considered at high risk of not transitioning successfully, namely Angola, Congo, Nigeria, Papua Guinea and Timor-Leste. The Board had also asked the Secretariat to develop a potential approach to post-transition engagement.
- 8.2 He recalled that he had presented some initial thinking on this approach to the Board at its meeting in June 2017 and that the approach being presented now is consistent with that as the Board had generally seem comfortable with it.
- 8.3 Santiago Cornejo, Director, Immunisation Financing & Sustainability, presented the approach to the PPC as outlined in Doc 08. He highlighted that sustainability is a core principle of Gavi's model, recalling that Gavi has been evolving and improving its approach and that the proposed approach to sustainability is unique and represents an experiment for both Gavi and the broader global health community.
- 8.4 He provided an overview on the countries that will have transitioned by 2020, presented the scenarios for engagement as they had been presented at the June 2017 Board meeting, and outlined the principles which had been taken into consideration when putting together the proposed approach for this meeting. He outlined the post-transition options in terms of ongoing non-financial engagement, catalytic vaccines investments, catalytic SFA investments and tailored post-transition strategies. He indicated that there is of course the option



to preserve the status quo, and requested the PPC also to consider an amendment to the limitation of the current “grace year” rule.

- 8.5 Finally, he indicated that the PPC’s guidance was being asked in relation to potential post-transition support specifically for Congo Republic and Ukraine.

### *Discussion*

- Comments which had been shared with the Chair in writing by Edna Yolani Batres, as she had been unable to attend the second day of the meeting, were shared with the PPC.
- Some PPC members expressed concerns that the paper did not clearly set out the problem statement nor fully address the fact that it did not seem to take into account the role of Alliance partners who remain engaged with countries post-transition, or the role of manufacturers in relation to price agreements which are already in place for countries post-transition.
- It was suggested that it would be useful in this context of this discussion to have a broader analysis that looks not only at post-transition countries but middle-income countries that have similar systems and GNI per capita to post-transition countries.
- PPC members noted that Gavi is a pathfinder in terms of its transition policy which aims to work with countries to help them to transition both programmatically and financially and that overall great work is being done in monitoring this and mitigating risks
- It was proposed that it would be useful for the PPC to have for discussion at its next meeting information in relation to the proposed high-level political advocacy strategy that needs to be put in place. The importance also of ensuring that countries understand that they are themselves accountable for successful transition was highlighted.
- In relation to the proposal to consider an amendment to the “grace period” there were quite differing views among PPC members. Some felt that this was not acceptable as it would require a modification to the eligibility and transition policy which had been approved by the Board. Others felt that Gavi should strive to ensure that countries can effectively make decisions and that if the “grace period” is forcing some perverse incentives, as would appear to be the case, then opening it up might allow countries to make more informed decisions and give them some flexibility until the end of the transition period. Following discussions, the PPC came to the consensus that they would not make any recommendation to the Board at the moment in relation to amending the current provisions.
- PPC members were supportive of the proposal to continue to engage with countries post-transition on a non-financial basis.

- In relation to catalytic vaccine investments it was agreed that it would be useful for the PPC to have a more detailed analysis on the options for discussion at their meeting in May 2018.
- A number of concerns were raised in relation to the proposal to have tailored post-transition support for high-risk countries and it was agreed that a more detailed analysis of the options should be undertaken for consideration at their next meeting in May 2017. Participants provided guidance on a number of issues which should be included in the analysis and highlighted the importance of considering where a number of issues might already be addressed through existing Gavi policies, strategies or other mechanisms.
- In relation to engagement with Congo Republic and Ukraine, PPC members felt that Gavi should continue to engage in political dialogue with Congo Republic, but did not feel that there should be further engagement with Ukraine at this stage.
- PPC members regretted that the SAGE MIC strategy has not really been followed up on and it was agreed that this is not something for Gavi to take on board during this strategic period but perhaps something that can be discussed in the context of the discussions that will soon start in relation to Gavi's strategy post-2020.

#### **Decision Four**

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

- a) **Request** the Secretariat to engage with Gavi Alliance partners in high-level political advocacy and undertake more detailed analysis of the risks to successful transition in Angola, East Timor and Congo and consider the options for how/whether these risks could be mitigated by the Gavi Alliance for consideration by the Board in June 2018. This analysis should include:
  - Whether programmatic risks are occurring in these countries during the transition phase.
  - An assessment of the impact of mitigation strategies outlined in the Transition Policy, Partners Engagement Framework, the approach to ensuring Access To Appropriate Pricing for Phase 3 countries.
  - Is the country on a good trajectory with respect to financial sustainability?
  - Has the country demonstrated political will?
  - Could further potential actions from the Gavi Alliance help to mitigate these risks?
- b) **Approve** continued Gavi Alliance engagement on a non-financial basis with Phase 3 countries and, where exceptionally required, fund targeted time-limited technical assistance to such countries under the Partners Engagement Framework.

- c) **Request** the Secretariat to analyse how Alliance mechanisms to support transitioned countries are working and identify any gaps and also analyse mechanisms being used by other non Gavi-eligible middle income countries and report back to the PPC.

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## **9. Successfully transitioning Nigeria & Papua New Guinea from Gavi support**

- 9.1 Seth Berkley, CEO, introduced this item, indicating that slightly different approaches were being proposed for Nigeria and Papua New Guinea (PNG). He highlighted in particular that the risks for inaction in Nigeria are very high, not just for Nigeria, but for the region and the global community. He informed PPC members that from numerous meetings he has had in Nigeria there does appear to be genuine commitment to effecting change among the current leadership.
- 9.2 Pascal Bijleveld, Director, Country Programmes, presented information on the current Nigeria context, Gavi's engagement to date with the country and a number of approaches for consideration in relation to engaging with Nigeria going forward to ensure its successful transition from Gavi support (Doc 09a).
- 9.3 He also presented information on PNG and the challenges it is facing (Doc 09b) which have impacted its EPI programme. He highlighted that the new Minister of Health has indicated that he would like to see PNG transition from Gavi support as planned at end 2020, but this will require Alliance partners to engage differently in the country.

### *Discussion – Nigeria*

- PPC members welcomed the proposed process whereby a proposal of the final strategy would be presented to the Board for decision in June 2018. They acknowledged the challenges that the country is facing and the risks that transition presents and agreed that it is an exception that requires a tailored approach.
- Differing views were expressed in relation to a possible vaccine-by-vaccine transition approach.
- Differing views were also expressed in relation to a possible state-by-state transition approach. It was agreed that this would warrant further analysis while keeping in mind that Gavi's general principle is a whole country approach, and that the negotiations going forward should ensure the engagement of all Alliance stakeholders.
- PPC members were generally open to further considering an increase in the HSS envelope as well as increasing TA support through both core and expanded partners.

- It was suggested that the proposals as outlined in Doc 09a were perhaps too project-oriented and that it would be useful to integrate them as part of a more strategic plan with a clear vision.
- PPC members agreed that the country needs to be held to account for the Gavi funds that have been misused in the past and that the implementation of any tailored strategy to ensure their successful transition from Gavi support should be conditional on full reimbursement of the balance of funds deemed to have been misused.
- PPC members considered a draft set of principles of engagement developed and shared with them by one PPC member during the meeting. PPC members agreed that it would be useful to ensure that there is a clear set of principles, also for the Board to consider, and agreed to further discuss during a PPC meeting convened by teleconference in advance of the Board meeting<sup>1</sup>.
- There appeared to be general consensus that a longer transition plan will be needed for Nigeria and it was agreed that it would be more appropriate for the Board to discuss the potential timeframe, as well as potential total financial engagement, during the closed session of their meeting in November 2017, so as to provide sufficient guidance to the Secretariat and Alliance partners on the parameters for negotiating the proposed transition plan for approval in June 2018.

### **Decision Five**

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

- a) **Request** the Secretariat to work closely with the broader Gavi Alliance partners to engage with the Government of Nigeria to develop a “Nigeria Transition Plan” for PPC review and Board approval in June 2018 that is based on the Gavi principles of country ownership and sustainability as well as the guidance provided by the PPC;
- b) **Allow** the Secretariat jointly with Alliance partners and other key stakeholders to engage with the Government of Nigeria on the Nigeria Transition Plan based on certain policy flexibilities, understanding that the Secretariat will need to conduct further analyses on these aspects in consultation with broader Alliance partners and that appropriate timelines and conditionalities are incorporated.

### *Discussion – Papua New Guinea*

- PPC members expressed support for the overall approach proposed to transition PNG successfully from Gavi support, and they applauded the work being done

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<sup>1</sup> Proposed principles were discussed by the PPC during a teleconference on 8 November 2017 and the record of that meeting is minuted separately.

by Alliance partners on the ground, and in particular that of the Australian Department of Foreign Affairs and Trade (DFAT).

- While welcoming the governments engagement to transition as planned at end 2020, PPC members agreed that expectations as to what can be achieved until then should remain realistic.
- Differing views were expressed in relation to the proposal to enable PNG to apply for new vaccine support until they transition out of Gavi support, in the context of the discussion earlier in the meeting where by it had been agreed that the “grace period” should not be extended for post-transition countries.
- PPC members noted that it had not yet been decided how additional HSS funding would be channelled to the country and that this would require further discussions.
- The PPC was unable to reach consensus on a) iii) of the recommendation below and a minority position expressed by Jean-François Pactet, representing the donor constituency anchored by Germany, will be reported to the Board.

### **Decision Six**

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

- a) **Approve** the following measures as mitigation strategies for risks to Papua New Guinea’s (“PNG”) sustainable transition:
  - i. HSIS: Increase the HSS funding ceiling from US\$ 6 million to up to US\$ 12 million for the remaining period of HSS support and allow Gavi funds to be used also for selected recurrent outreach costs, contingent on the Government committing that these costs categories will be budgeted post-transition;
  - ii. MR Campaign: Allow PNG to apply for a Measles Rubella campaign in 2018 and authorise the CEO, based on an IRC recommendation, to allocate associated operational support costs at a level required by the circumstances in PNG, including for staffing costs;
  - iii. NVS: Allow PNG to apply for new vaccine support until they transition out of Gavi support;
  - iv. Co-financing: Allow the Secretariat to negotiate with PNG to adjust its co-financing rates to fit within its trajectory towards successful transition by 2021.
- b) **Request** the Secretariat to report to the PPC and Board in 2019 on progress.

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## **10. Update on Key Recommendations of the Independent Review Committee and High Level Review Panel**

- 10.1 Bolanle Oyeledun, Chair, Independent Review Committee (IRC), and Anuradha Gupta, Deputy CEO, presented the report of the IRC and the work conducted under the High Level Review Panel (HLRP) (Doc 10). They provided an overview of the number of applications reviewed by the IRC since November 2016, on the IRC's participation in the Country Engagement Framework (CEF) pilot in six countries, as well as the HLRP review of 21 grant renewals, focusing on PEF priority countries. They presented the key findings relating to measles campaigns, HPV national introduction, CCEOP applications and data quality, providing recommendations for areas of improvement.
- 10.2 Lessons learned from the HLRP reviews were shared on creating system efficiencies in relation to vaccine supply, country performance metrics and HSS investments.
- 10.3 Finally, the PPC was requested to consider a proposal to recommend to the Board that it approve flexibilities to the Gavi review mechanisms relating in-country and ad-hoc reviews.

### *Discussion*

- PPC members welcomed the presentation and the fact that flexibilities are being proposed that adapt review processes to specific country situations.
- In relation to some questions expressed by PPC members whereby it appeared that there was a move back towards a Geneva-based review process, the Secretariat clarified that the CEF process comprises four elements, namely planning, proposal development, review and oversight. While there is a focus on the country-centric approach for each of these components, taking into account certain considerations such as independence, consistency of decision and resources, some of the reviews will continue to be carried out in Geneva.
- PPC members noted that the wording in the presentation relating to the IRC recommendation on HPV and HIV positive girls and young women was misleading and it was agreed that this should be corrected.

### **Decision Seven**

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

- a) **Approve** the flexibilities to include in-country reviews and ad hoc review by IRC members as part of the Gavi review mechanisms for country applications, as described in Section 5 of Doc 10; and
- b) **Request** the Secretariat to update any relevant governance documents to enable the implementation of these flexibilities and present the updated

governance documents for review and approval by the appropriate governance bodies.

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## **11. Risk & Assurance Report**

- 11.1 Jacob van der Blij, Head of Risk, and Alex de Jonquières, Chief of Staff, presented this item to the PPC (Doc 11) requesting the Committee's guidance on the 11 top risks within the PPC's purview as described in the draft Risk & Assurance report, and on any concerns that there might be on risk exposures which are clearly outside Gavi's risk appetite and if any of the risks require a more in-depth discussion by the Board in November 2017 or at a future date.
- 11.2 In response to a request from the PPC during a previous meeting, they presented Zambia as a case study, and they also informed the PPC on feedback that had been received from the Audit and Finance Committee (AFC) during its own meeting the previous week on the Risk & Assurance report.

### *Discussion*

- PPC members were broadly comfortable with the ranking of programmatic risks as presented. Some questions were raised on the calibration of programmatic versus corporate risks, the interdependencies and overlap between risks, the reason for the slight decrease in risk exposure related to sustainable transition, and on the precise definition of the risk on the ability to reach the under-immunised.
- Some PPC members suggested that additional risks might be considered such as the inability to expand to new age group platforms, weak surveillance and polio transition. The Secretariat noted that these had been captured as sub-risks or drivers of existing top risks, but that suggestions to define these as stand-alone top risks will be explored further. It was pointed out that the risks presented are risks to Gavi and that it would not be appropriate to include risks which would be outside of Gavi's remit.
- Some PPC members suggested that it might be useful for the Board to have a future in-depth discussion on the risk related to ability to reach the under-immunised, as this is one of the risks which is outside risk appetite.
- Another suggested was the vaccine confidence risk, especially since changes in exposure could potentially move quickly.

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## **12. Review of decisions**

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

### **13. Any other business**

- Before concluding the meeting the Chair informed PPC members that he had been invited in his capacity as PPC Chair to attend the next meeting of the Governance Committee in the context of the recent review of the PPC Charter and that he would report back to the PPC on the outcome of that meeting.
- After determining there was no further business, the meeting was brought to a close.

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Mrs Joanne Goetz  
Secretary to the Meeting



## Attachment A

### Participants

#### Committee Members

- Richard Sezibera, Chair
- Dure Samin Akram
- Edna Yolani Batres (Day One)
- Lindsey Dietschi
- Abdul Wali Ghayur
- Rama Lakshminarayanan
- Jason Lane
- Lene Lothe
- Susan McKinney
- Violaine Mitchell
- Robin Nandy
- Jean-Marie Okwo-Bele
- Jean-François Pactet
- Adar Poonawalla
- Helen Rees
- Seth Berkley, Chief Executive Officer
- Alejandro Cravioto

#### Regrets

- Umyy Ally Mwalimu
- Syed Monjurul Islam

#### Committee Member Elect

- An Vermeersch

#### Other Board Members Attending

- Danny Graymore (Agenda Items 8, 9 and 10)

#### Guests

- Diana Chang Blanc, WHO (Day One)
- Michel Zaffran, WHO (Agenda Item 5)
- Mike McGovern, Chair, GPEI TMG (Agenda Item 5)

#### Observers

- Stephen Karengera, Special Adviser to the PPC Chair
- Rolando Pinel, Special Adviser to Edna Yolani Batres
- Sue Graves, Australia

#### Gavi Secretariat

- Anuradha Gupta
- Alex de Jonquières
- Joanne Goetz
- Judith Kallenberg
- Hind Khatib-Othman
- Johannes Ahrendts (Agenda Item 2)
- Pascal Bijleveld
- Alan Brooks
- Sarah Churchill (Agenda Item 10)
- Mirjam Clados
- Santiago Cornejo
- Anne Cronin (Agenda Item 3, 4)
- Adrien de Chaisemartin
- Hope Johnson (Agenda Items 2, 4, 6, 7)
- Melissa Ko (Agenda item 6)
- Patricia Kuo (Agenda Item 10)
- Wilson Mok (Agenda item 7)
- Marie-Ange Saraka-Yao (Agenda items 8, 9)
- Antara Sinha
- Stephen Sosler (Agenda Items 5, 6)
- Eelco Szabo (Agenda Items 3, 4, 6, 7, 8, 9)
- Nicolas Theopold (Agenda Item 2)
- Michael Thomas
- Jacob van der Blij (Agenda Items 2, 3, 4, 8, 9, 11)