GAVI Alliance Programme and Policy Committee Meeting

28-30 September 2011
Geneva, Switzerland

FINAL MINUTES

1. Chair's report

1.1 Finding a quorum of members present, the meeting commenced at 9.15 Geneva time on 28 September 2011. Gustavo Gonzalez-Canali, the Chair of the Programme and Policy Committee, chaired the meeting.

1.2 The Chair welcomed Klaus Stohr as a new member to the Committee. He also welcomed Seth Berkley, GAVI's new CEO, to his first meeting. He thanked Helen Evans, Deputy CEO, for her service over the past year as a Committee member.

1.3 The Chair also mentioned that this would be the final Committee meeting for Leone Gianturco, Magid Al-Gunaid, Rama Lakshminarayanan, Nguyen Tran Hien and Joan Awunyo-Akaba. He thanked the departing members for their service and commitment to the GAVI Alliance generally and the Committee in particular.

1.4 In accordance with the Conflict of Interest Policy, standing declarations of interest (Doc #01a) were tabled to the Committee so that any potential interests in the matters to be discussed could be transparent and addressed in compliance with the Policy. The Chair announced, upon advice from the Managing Director, Law and Governance, that during the discussion on the vaccine supply and procurement strategy, representatives of the vaccine industry would attend the Secretariat's presentation and be allowed to present their viewpoints before being requested to leave the room for the remainder of the discussion and any decision to be taken.

1.5 The Chair referred to the minutes of the Committee's meeting on 9 May 2011 (Doc #01b). These minutes were approved by no objection on 15 July 2011 under section 2.7.3.3 of the By-Laws.

1.6 Nina Schwalbe, Managing Director, Policy and Performance updated the Committee on ongoing tasks assigned to it and progress to date, including progress on the partner support task team; questions around the possibility for countries to self-procure vaccines; and review of the vaccine introduction grant. She also noted that the Secretariat has reviewed the impact on

eligibility changing the GNI per capita threshold to US$ 2,000 and would be presenting this analysis to the Board in November.

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2. Update from the Secretariat

2.1 The CEO updated the Committee on the Secretariat's activities since the Committee's last meeting with the success of the pledging conference in June 2011.

2.2 Recently, the Executive Committee approved a record number of vaccines introductions. This will require the Secretariat and the Alliance partners to focus their efforts on monitoring very closely the implementation of these new programmes and to increase its knowledge of what is happening on the ground and how countries are delivering results. To address various issues facing countries, GAVI should consider developing a more tailored approach to address the different needs of countries. This should include coordination with partners focusing on other vaccine preventable diseases, such as polio.

2.3 The Secretariat is actively engaged with key Alliance members in critical market shaping issues, managing the sometimes conflicting goals of ensuring security of supply and minimising the cost of vaccines. To this point, the Secretariat will need to expand in-house expertise in certain technical areas to be able to better manage for results.

2.4 Finally, he highlighted the critical role that research studies will play in helping to provide GAVI and countries with information to make better informed decisions around prioritisation, presentation and other important factors. He noted that a recommendation on options for GAVI engagement will be presented to the PPC for review in the spring.

Discussion:

- Committee members noted their appreciation of the various reports and materials. They also expressed their appreciation of the CEO's perspective and suggested that future reports include additional commentary on the challenges facing GAVI.

- Some members commented that immunisation programmes are becoming more complex and are no longer limited to the EPI structure. With the increase in complexity, the Alliance needs to plan and prepare now for 2012 introductions to pre-empt potential problems.

- Other issues raised included the need to focus on the added value of the Alliance and its partners; the importance of quality data sources at country level; GAVI's strategy for graduating countries; and the role GAVI should serve, if any, in regards to lower middle income countries.

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3. Programme Funding

Mercy Ahun, Managing Director, Programme Delivery and Clifford Kamara, Chair of the New Proposal and Monitoring Independent Review Committees informed the PPC on the outcomes of the recent reviews (Doc #3).

Discussion

- GAVI's portfolio is expanding as new vaccines become available. As that happens, GAVI needs a clear agenda to remain focused on its priorities and deliver the greatest return on investment. As a result, the work load for stakeholders is expanding and this will have an impact on the business plan.

- A question was raised as to whether the Secretariat should expand its role in the review of applications to ensure that applications are not exclusively judged on the basis of a desk review of documentation.

- The Committee considered that the slow disbursement of funds for HSS is closely connected to the need to ensure appropriate safeguards are in place.

- Committee members expressed the concern over obtaining quality data at the country level and questioned to what extent other tools, such as independent surveys, could be used.

- The Committee questioned what role GAVI could play, potentially through cash funding or other mechanisms to address equity gaps.

- Some Committee members noted that the ability to introduce more than one new vaccine in a short time period should be analysed on a country-by-country basis. However, multiple introductions should also be viewed as an opportunity, and not only a risk. Committee members also supported the concept of requesting disaggregate data on gender, suggesting that GAVI may want to start with a subset of countries only.

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4. Programme update: AVI and country programmes

AVI

Jon Pearman, Director, AVI, Carsten Mantel, WHO and John Wecker, PATH updated the Committee on AVI activities, including recent pneumococcal and rotavirus vaccine introductions.

Discussion

- Committee members appreciated the update. They also expressed appreciation for the inclusion of Meningitis A (MenA) and Yellow Fever (YF) in the presentation and requested to receive more information on these activities in future reports.

- Some members commented that surveillance data and special studies will be necessary as new vaccines are introduced to allow countries to make more informed decisions on impact and value for money, which could lead to faster uptake and post-graduation commitment to the new vaccine. Further, the Committee requested the Alliance explore opportunities to streamline surveillance activities and work with other partners so that countries do not end up with parallel surveillance teams for each new vaccine introduced. Members requested that the next AVI report present a long term look at surveillance and asked to receive the results of the ongoing special studies prior to the spring of 2012 to inform decision-making.

- Committee members requested more information on AVI-TAC, how it is working, how much it feeds into in-country coordination and more on regional and sub-regional activities.

- With respect to supply shortage, the PPC asked about lack of product availability for the GAVI market.

- Given that some countries during their introduction of the pneumococcal vaccine provided vaccinations to children outside of the EPI schedule, in a supply constrained environment, GAVI should develop clear guidelines on GAVI-supported vaccines and communicate those guidelines clearly to countries.

- In response to questions, the Secretariat explained that the vaccine allocation process is being used, along with other considerations, in cases where demand is greater than supply to determine the order and time frame for countries to receive the product.

Country programme update

Mercy Ahun and Paul Kelly, Director, Programme Delivery updated the Committee on country programmes, focusing on vaccine coverage, health system strengthening activities, and the status of the co-financing programme.

Discussion:

- Committee members expressed concerns around sustainability. GAVI will need to creatively address issues relating to graduating countries.

- The Committee asked about the role and position of the IRC as the GAVI Alliance moves toward the Health Systems Funding Platform (HSFP) for health systems support.

- Committee members expressed appreciation for the country case studies presented in the Committee paper and requested case studies not only the good performers but also on those not performing as well and in general to have more details on countries with critical weaknesses.

5. Preliminary results: analysis of countries with low DPT3 Coverage

The request for an analysis of countries with low DTP3 coverage grew out of the work of the previous GAVI cash based task team when the Committee at its meeting in May 2011 asked countries and their partners to carry out analysis to establish the main reasons why countries have DTP3 coverage rates below 70 percent. Wim Van Lerberghe, WHO, presented a possible methodology based on analysis carried out by WHO from one country.

Discussion:

- The Committee found the analysis interesting, however, the Committee requested that WHO, together with partners, endeavour to identify specific in-country issues and bottlenecks on a country-by-country basis that needed addressing while at the same time identifying issues that may be addressed systematically.

- Members noted that the report should address equity issues at the country level and should tie into issues addressing GAVI's strategy with fragile and underperforming states.

- The Committee suggested the team also analyse countries and districts which had been successful in order to compare and contrast against. They also reiterated a previous request to ensure engagement by UNICEF, civil society and other partners in the analysis.

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6. Supply and Procurement Strategy

6.1 In February 2010, the Committee formed a new vaccine supply and procurement strategy task team to update its supply strategy for 2011-2015. The Task team presented its recommendations to the Committee at its meeting in May 2011. At that time, the Committee endorsed the proactive market shaping approach with an expanded set of supply and procurement mechanisms suggested in the paper. The Committee, however, requested the Secretariat to redraft the supply and procurement strategy paper based on comments made at the meeting and to make the revised draft publicly available for comments by GAVI stakeholders and interested parties.

6.2 Aurélia Nguyen, Director of Policy, presented the revised strategy which includes new sections on monitoring and evaluation, roles and responsibilities as well as further explanations on the roadmaps, graduating countries and ensuring sustainability.

6.3 Vaccine industry representative Committee members, Suresh Jadhav and Klaus Stohr were present during the presentation, shared their views following the presentation and then left the room while the Committee continued to deliberate and decide on the strategy.

Discussion:

- Both industry representatives expressed agreement in principle with most of the elements of the strategy prior to providing their comments.

- The representative of developing country vaccine industry noted the pressure on the developing country manufacturers to lower prices. He also said that vaccine availability is most paramount. To that end, he noted manufacturers would appreciate more transparency into and to receive information on major quality issues to respond to situations as they arise.

- The representative of industrialised country vaccine industry highlighted that achieving and preserving the right balance of the strategy's objectives will be challenging but vital to ultimate success. His constituency suggests a stronger emphasis on quality and that the roadmaps proposed in the strategy should address how the criteria and risks in relation to the different objectives are balanced.

- The representatives of vaccine industry then left the room for the remainder of the discussion and the decision.

- The Committee noted the importance of ensuring affordable and sustainable prices for graduating countries. The Committee also suggested that the strategy recognise the need to strengthen procurement capacities in graduating countries as part of activities supported by GAVI Alliance members.

- A number of Committee members requested that a more in-depth discussion be initiated on possible GAVI engagement with lower middle income countries that are not currently eligible for GAVI financial support, taking into account that large numbers of unimmunised children are living in the poorest sections of these countries.

- Noting the importance of transparency, information sharing and oversight, the Committee requested the Secretariat regularly report to the PPC progress on the implementation of the strategy.

Decision One

The GAVI Alliance Programme and Policy Committee:

- **Recommended** that the Board approve the vaccine supply and procurement strategy for the period 2011-2015 as further revised during the PPC Meeting (Doc 06a).

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7. Next steps on new vaccine windows

7.1 In 2008, the GAVI Board approved adding to its portfolio new vaccines covering human papilloma virus (HPV), Japanese encephalitis (JE), rubella and typhoid. At its meeting of 9 May 2011, the Committee endorsed a process for developing implementation strategies and guidelines for the four vaccines such that applications could be accepted by 2012 in some cases.

7.2 Mr. Pearman discussed the strategy for introducing each of the four vaccines. He noted that the model for assessing rubella impact was being revised based on the new WHO strategy and thus the metrics included in the paper should be removed from consideration.

7.3 Vaccine industry representative Committee members, Suresh Jadhav and Klaus Stohr were present during the presentation and shared their views following the presentation before leaving the room for the remainder of the discussion and the decision.

Discussion:

- The representative for industrialised country vaccine industry expressed support for the proposal, noting that it provides the immunisation community with assurances. He also recommended that price related discussions continue to be handled through UNICEF to avoid potential anti-trust issues.

- The representative for developing country vaccine industry supported introducing the new vaccines but cautioned that the decision should be underpinned by sound financial analysis. He also noted to the importance of maintaining coverage rates after graduating from GAVI support.

- (Manufacturer representatives left the room for the remainder of the discussion and the decision.)

- The Committee noted that GAVI's vaccine strategy needs to be holistically reviewed also taking into account potential future vaccines such as IPV and malaria

- The Committee discussed in detail the costs involved in implementing the HPV vaccine, particularly given that it would be delivered outside the EPI schedule. The Committee stressed that the vaccine introduction grant will need to be re-examined to better understand the role it will play in helping countries implement the programmes for the new vaccines.

- For HPV, the Committee expressed a need for stringent criteria for the IRC to use when assessing applications from countries to ensure countries requesting HPV vaccines have the capacity to implement appropriately.

- The Committee noted that a combination rubella-measles vaccine will assists in efforts to control measles, which the Committee considered as an added

benefit. The Committee suggested that the Secretariat explore possible areas of partnering with the Measles Initiative.

- The Committee noted that efforts should be made to ensure that countries receiving support for rubella campaigns did indeed also support routine introduction.

- The Committee noted the high importance of the JE vaccine to GAVI eligible countries in South East Asia. The potential implementation strategy, the vaccine landscape and cost implications were discussed. Given that there is not currently a prequalified vaccine for JE, the Committee concluded that it would not recommend opening a window for JE at this time.

- With regard to typhoid vaccines, the Committee agreed that the implications of opening a window for a polysaccharide vaccine as a bridging strategy to introduction of a conjugate vaccine were not clear given the absence, to date, of reliable data on relative and absolute disease burden. The Committee identified as a major weakness the fact that without a definitive timeline for development of the conjugate vaccine, a polysaccharide vaccine would need to be re-administered regularly. Yet, one member maintained that the polysaccharide vaccine could be a cost-effective solution especially in urban slums, and supported the need to review this issue in the near future when reliable data will be available, and if the uncertainty about the development of conjugate vaccines persists.

- The PPC member from the Bill & Melinda Gates foundation presented information on other vaccines under development and timelines. The Committee noted that GAVI's vaccine strategy needs to be holistically reviewed also taking into account future vaccines such as IPV and malaria and their potential impact on the budget.

- It was noted that countries need reliable data in order to make informed decisions around vaccine choice and that investments in special studies will be critical to answering these questions.

Decision Two

The GAVI Alliance Programme and Policy Committee:

- **Recommended** to the Board that it open funding windows for HPV and rubella vaccines such that the GAVI Secretariat can invite country proposals for support in 2012.

- **Recommended** to the Board that it note that JE is a critically important vaccine, particularly for South East Asia. GAVI should consider opening a window once an appropriate vaccine is prequalified. Continued efforts are needed regarding surveillance.

- **Recommended** to the Board that it not to revisit its previous decision on typhoid noting that the Alliance looks forward to the development of an appropriate conjugate vaccine.

- **Requested** the Secretariat to work with technical partners, to develop an HPV pilot programme following the Board meeting in November 2011.

- **Requested** the Secretariat to update the "Next steps on new vaccine" paper with the following:

    - Detailed programme implementation costs for HPV and appropriate levels for GAVI support.

    - Clearly defined filters in order for countries to be approved for the HPV vaccine.

ACTION ITEM

- With regard to rubella, the impact metrics presented in the Board paper should be updated prior to submission to the Board.

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8. Performance based funding

In 2010 the Board approved the Incentives for Routine Immunisation Strengthening (IRIS) as a pilot and asked the Committee to define implementation of the pilot. In response to this request, the Committee convened the IRIS Pilot Task Team. The scope of the task team was expanded following the July 2011Board request to development of options for performance incentives for GAVI's cash support through the platform in coordination with the design of IRIS. The Task Team proposal was presented by Peter Hansen, Director, Monitoring and Evaluation.

Discussion:

- The Committee supported the elements of the design the task team presented and expressed its appreciation of the good work of the task team, noting in particular the alignment with country processes and plans, the inclusion of measles as an indicator and the equity considerations.

- The Committee noted that implementation of the design will require reliable data and expressed concerns about the risks associated with using weak data as the basis for payments. This highlighted the Alliance's need to invest in innovation to improve data quality at the country level.

- The Committee requested specific changes to the paper to be incorporated in the final version going to the Board including a request to specify that for the highest coverage countries, 90 percent of districts should have coverage of greater than 80 percent in order to be eligible for a reward.

- In recognition that some countries may need to have their grant agreement and payment conditions modified following exceptional events beyond their control, a force majeure clause should be added.

- The recommended approach would not fit all countries, including fragile and post-conflict countries. It is important to retain flexibility in tailoring the design to meet country circumstances as appropriate.

Decision Three

The GAVI Alliance Programme and Policy Committee:

- **Recommended** to the Board that it decide not to proceed with IRIS as a standalone window of support;

- **Recommended** to the Board that it request the Secretariat to roll out the Health Systems Funding Platform in accordance with the design summarised in box one of the report on performance based funding (Doc 08a) starting in 2012 for countries to use as their existing cash support elapses.

ACTION ITEMS

- Request the Secretariat to develop a policy that clearly defines fragile and under-performing countries and the GAVI Alliance's approach to supporting such countries to be presented to the Board in 2012 following PPC review.

- Request the Secretariat to explore improvements in data quality by looking at potential investments in innovative verification techniques.

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9. Large Countries of India and Nigeria

In March 2011, the Committee approved the terms of reference of the Large Country Task Team chaired by Mickey Chopra to develop a strategy to guide future GAVI support to India and Nigeria. The task team conducted an in-depth review of the status and utilisation of GAVI support and on-going activities in both countries and conducted extensive country and stakeholder consultations. The task team proposal was presented by Mercy Ahun and Mickey Chopra, UNICEF. They highlighted that the consultation in country at a very senior level was significantly helped by the fact that the task team was comprised of senior staff from a number of key agencies.

Discussion:

- The Committee questioned the alignment between the strategy put forward on the two large countries with GAVI's strategy to address fragile and under-performing countries.

- A number of Committee members expressed concern over some of the specific recommendations for each country, noting that GAVI should focus on what was truly catalytic. Specifically, a significant number of Committee members were not in favour of setting up a guarantee for vaccine procurement for Nigeria, and were also concerned about possible moral hazard consequences.

- The Committee discussed the idea of potentially waiving the thresh hold filter for large countries or looking at the filter on a sub-national level. The Committee encouraged the creation of a formal relationship, thereby establishing a partnership approach and favoured the idea of providing more technical assistance to India and Nigeria. The Committee highlighted that the role of CSOs will be critical to achieving success in both countries.

- The Committee also discussed the US$ 350 million cap for GAVI support to India. Some Committee members favoured revising the cap upwards or removing the cap altogether.

- The Committee noted the excellent work of the task team and the positive momentum it had generated. It stressed that GAVI should maintain this momentum and enthusiasm that has been gained and continue the discussion in country, but that the details of the recommendation needed further work on how they would be implemented.

ACTION ITEM

- The PPC agrees that these countries need a tailored approach and asked the Secretariat to work with the countries and partners to develop a plan of action.

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10. Dr. Gonzalez' proposal on co-financing

In June and December 2010, the Board approved a revised co-financing policy, which is to be implemented starting in 2012. Immediately prior to the December Board meeting, the Chair of the Committee received a letter from Dr. González-González, the Board member representing Latin America and Europe, expressing reservations with the revised co-financing policy and proposing an alternative approach. The Board requested the Committee to review the concerns raised. At the request of the Committee chair, the Secretariat prepared an analysis of the proposal and presented a report comparing the Board approved co-financing policy with the proposal presented by Dr. González-González. A presentation was given by Santiago Cornejo, Senior Specialist, Country Co-financing.

Discussion:

- The Committee discussed the proposal and ultimately decided that it would not recommend that the Board revise the co-financing policy.

- The Committee acknowledged the work that Dr. González-González has done on this issue and suggested that González-González's proposal be looked at again during the next revision of the co-financing policy in 2014.

Decision Four

The GAVI Alliance Programme and Policy Committee:

- **Decided** upon careful consideration of the proposal of Dr. Guillermo González González for an alternative approach to GAVI's co-financing policy, not to make any recommendations to the Board for a change to the Co-financing Policy that the Board adopted at its meeting in November 2011, this can be considered as part of the review of the co-financing policy in 2014.

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11. Business Plan

11.1 Helen Evans, Deputy CEO gave an update on progress on the implementation of the business plan.

Discussion:

- The Committee welcomed the new business plan approach and appreciated the report, noting that the business plan approach was much more conducive to focusing on deliverables and results.

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12. Prioritisation – Next Steps

In June 2010, the GAVI Alliance Board approved a pilot prioritisation mechanism to be used in case the GAVI Alliance would have insufficient funding to support all applications that the Board would have otherwise approved in a given application round. The prioritisation mechanism was subsequently extended to include metrics on measles second dose, meningitis A, and yellow fever vaccine support. Given GAVI's current levels of funding, there is currently no need to apply the prioritisation mechanism to the vaccine proposals submitted in the 2011 application round. However, the mechanism should be maintained to be applied if necessary. The Secretariat will coordinate a review of the pilot and revise the mechanism according to future needs.

Discussion:

- The Committee agreed with completing the analysis to see how the final scores would have come out had the mechanism been needed for the 2011 application round. Committee members agreed that the new vaccines for which a funding window will be opened should be added to the mechanism.

- The industrialised country manufacturing representative noted that the application of the prioritisation mechanism created uncertainty and lack of predictability. Others pointed out that the presence of a prioritisation policy and mechanism is beneficial precisely because it provides a systematic, transparent and predictable basis for making funding decisions if and when finances are insufficient to meet demand.

Summary of Action Items

The PPC agreed that the Secretariat should:

1. Work with technical partners, to develop an HPV pilot programme following the Board meeting in November 2011.

2. Update the "Next steps on new vaccine" paper with the following:
   - Detailed programme implementation costs for HPV and appropriate levels for GAVI support.
   - Clearly defined filters in order for countries to be approved for the HPV vaccine.

3. With regard to rubella, the impact metrics presented in the Board paper should be updated prior to submission to the Board.

4. Develop a policy that clearly defines fragile and under-performing countries and the GAVI Alliance's approach to supporting such countries to be presented to the Board in 2012 following PPC review.

5. Explore improvements in data quality by looking at potential investments in innovative verification techniques.

6. Move forward with setting up a working group to coordinating GAVI's engagement in health systems.

7. Clarify the policy on whether or not GAVI will support an application for a vaccine from a country which has already introduced that vaccine (with their own or donor resources).

8. With regard to support for rubella, develop options for working with countries to ensure the likelihood that they will follow up with routine introduction after completion of the campaigns.

9. Present the Board with strategic financial and vaccine introduction forecasts, including information on potential new vaccines under development to enable the board to put the current requests into perspective.

10. Work with India and Nigeria and partners to develop a plan of action because the PPC agrees that these countries need a tailored approach.

There being no further business, the meeting was brought to a close.

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Ms Debbie Adams
Secretary to the Board

Participants

Committee Members

- Gustavo Gonzalez-Canali (Chair)
- Magid Al-Gunaid
- Joan Awunyo-Akaba
- Mickey Chopra
- Paul Fife
- Leone Gianturco
- Nguyen Tran Hien
- Suresh Jadhav
- Rama Lakshminarayanan
- Steve Landry
- Susan McKinney
- Anders Nordström
- Jean-Marie Okwo-Bele
- Anne Schuchat
  Klaus Stohr

Expert Advisor

- Helen Rees (non-voting member representing SAGE)

Regrets

- Ashutosh Garg

Other Board members present

- Seth Berkley (non-voting)

GAVI Secretariat

- Debbie Adams
- Mercy Ahun
- Anthony Brown
- Santiago Cornejo
- Adrien de Chaisemartin
- Par Eriksson
- Helen Evans
- Johanna Fihman
- Eliane Furrer
- Peter Hansen
- Louise Imbsen
- Paul Kelly
- Ranjana Kumar
- Susie Lee
- Katie Moore
- Meegan Murray-Lopez
- Aurélia Nguyen
- Jon Pearman
- Nina Schwalbe
- Bakhuti Shengelia
- Laura Stormont
- Daniel Thornton

Guests

- Clifford Kamara, Chair, Independent Review Committee
- Willem Van Lerberghe, WHO
- Carsten Mantel, WHO
- John Wecker, PATH