Programme and Policy Committee (PPC) Meeting 1-2 October 2009 Geneva

Participants

PPC members

Sissel Hodne Steen (Chair), Joan Awunyo-Akaba, George Bickerstaff, Ashutosh Garg, Mickey Chopra, Majid Al-Gunaid, Suresh Jadhav, Rama Lakshminarayanan, Steve Landry, Susan McKinney, Jean-Marie Okwo-Bele, Olga Popova, David Salisbury (non-voting)

Observers

Ondrej Simek Jos Vandelaer

Secretariat

Helen Evans, Nina Schwalbe, Mercy Ahun, Lisa Jacobs, Gian Gandhi, Carole Presern (for HSS), Craig Burgess (for HSS), Pooja Mall (for workplan), Joelle Tanguy (for prioritisation and resource allocation), Ulf Herzer (for prioritisation and resource allocation)

With Regrets

Aldo Tagliabue, John Clemens

1. Eligibility Policies

Eligibility Task Team Chair Rama Lakshminarayanan introduced the topic and GAVI Senior Policy Programme Manager Gian Gandhi explained to the Committee the process, analysis, conclusions and recommendations of the Task Team. **Discussion followed:**

- Members agreed that GAVI needed to improve eligibility policies using simple and transparent metric that will be updated regularly and available from a third party standardised source that is comparable across countries, and has good data coverage across countries.
- On the issue of whether GAVI should focus on the poorest countries or the poorest people, the PPC reinforced their recommendation of June 2009. Some PPC members expressed concern about the numbers of unimmunised children in countries that may not meet national poverty indicators but have impoverished regions in which children are being underserved by the health system. However, in conclusion, members agreed that data at subnational levels is not sufficiently robust to allow for subnational support by GAVI and it is the responsibility of governments to allocate adequate resources to health and work towards equity within their own countries. The PPC recommended that the rationale for this recommendation be well explained in the paper for the Board.
- The Committee was split quite evenly on the question of whether to raise the GNI threshold for 2011 to US\$1500, which adjusts the previous threshold of US\$1000 in 2003 for inflation thereby keeping it constant in real terms; or to raise it to \$US2000 which keeps the size of the total birth cohort largely consistent with the one that exists for the current 72 countries as defined using the threshold of US\$1000 in 2003 terms. Issues of GAVI's commitment to reach the MDGs and the potential effects on procurement were discussed.

• The 70% DTP3 coverage 'filter' for introduction of new vaccines is a good idea as it sends the right signal that countries can qualify for support of new vaccines once basic vaccination is well in place. However, the rationale and evidence behind the choice of 70% needs to be better explained in the final submission to the Board. It should be noted that if GAVI does adopt this new requirement, GAVI needs to ensure that there is support in place for countries which fall below this rate to increase coverage.

The Committee agreed to recommend to the Board that the final submission on eligibility should include the following components:

- a) Gross National Income (GNI) per capita data (Atlas method, World Bank) should be used as the main indicator.
- b) There should not be sub-national eligibility as this is not consistent with fiscal federalism, subnational indicators are not standardised or widely available, and defining subnational units would be problematic. Finally, this approach would not be consistent with the overarching goal to focus GAVI support on the poorest countries.
- c) The eligibility threshold should be annually adjusted for inflation.
- d) The new threshold should be introduced as of 2011 (using 2010 World Bank GNI per capita data).
- e) Countries should have DTP3 ≥70% coverage (using WHO/UNICEF estimates) in order to be considered for introduction of new vaccines. Other filters should be developed for other GAVI windows.
- f) Given that JE, Men A and YF vaccine address epidemic diseases, failing to introduce the vaccine in one country increases the risk to neighboring countries thus the NVS filter should not apply to these vaccines.
- g) GAVI should identify a new budget cap for India for 2012-2015. The size of the budget cap should be subject to available resources, and based on projections of support to other countries.
- h) The PPC could not decide whether the new eligibility threshold should be \$1500 GNI or \$2,000 GNI, recognising good arguments for each. The final submission to the Board should present both options, clarifying the relative benefits of each. Further, WHO and UNICEF agreed to provide further analysis and arguments for their preferred option (\$2000) and if time allows, the PPC could have further discussions prior to the Board meeting to see if there were grounds for making a recommendation.

2. Graduation Policies

GAVI Senior Policy Programme Manager Gian Gandhi explained to the Committee the process, analysis, conclusions and recommendations of the Task Team. **Discussion followed:**

- There was significant discussion about the merits and risks of developing strategies to support middle income countries including the signals they might send to countries and industry, and whether it might dilute GAVI's mission.
- Committee members discussed whether there should be a 'grace period' to support financial sustainability after countries' income has rendered them ineligible for GAVI support.
- There was some discussion about whether the exploration of short term financial support and/or access to affordable prices to help graduating countries achieve financial sustainability would dilute GAVI's goal to focus on the poorest countries. The Secretariat committed that the

broader question of assistance to graduating countries and possibly even other lower middle income countries should be addressed as part of GAVI's strategic plan (2011-2015) development which will also be undertaken next year.

• It was recommended that the issue of whether/how GAVI can help graduating countries to access to affordable prices for vaccines (e.g. through pooled procurement) without direct GAVI subsidy should be undertaken as part of the Secretariat's work in 2010 when exploring how GAVI and others can create and sustain healthy markets for affordable vaccines. This will include appropriate consultation with industry.

The Committee agreed to recommend to the Board the proposed graduation policy principles which should include the following components:

- a) Countries should be informed as early as possible when they are expected to graduate from GAVI support and what that process will entail.
- b) After countries have graduated from GAVI support:
 - a. Commitments to graduating countries through 2015 should be honored.
 - b. No new applications should be submitted, but if countries have received a conditional approval from the IRC for a previously submitted application, this application can be finalised and approved in line with eligibility and prioritization policies within the year following graduation.
 - c. GAVI should not provide a 'grace period' other than that which is outlined above.
- c) GAVI should explore options to spread existing support or offer additional but short term financial support to assist the transition of graduating. This analysis should be conducted within the context of the prioritisation exercise and should be undertaken as part of the revision of GAVI's co-financing policy which must also consider the issue of graduating countries and ensuring they achieve financial sustainability.

3. Health System Strengthening Joint Platform

GAVI Managing Director of Special Projects, Carole Presern updated the Committee on the discussions to date on the potential for the HSS joint platform including the teleconferences with the special HSS advisors to the PPC. **Discussion followed:**

- PPC members voiced their appreciation for the flow of information provided by the Secretariat over the summer, including the active participation of the HSS advisers, multiple teleconference and documentation.
- The GFATM secretariat and Policy and Strategy Committee has had a different process and the discussions there have not reached the same level of consensus as within the PPC, and as a result, the GFATM Board may not be in as clear a position for a decision at its November meeting. This will represent a challenge in the synchronization of decisions by the two boards. Thus, GAVI Alliance Board should therefore be prepared to take a leadership role in the decision making process.
- PPC members sought clarity on the recent announcement at the UN General Assembly on a new donors' commitment for an expanded IFFIm for health systems. At this point, specifics are not available about funding flows or the exact nature of the announced commitments. It is apparent however that the commitments would be contingent upon a joint HSS platform; if the joint platform is not achieved, the funding might not materialise.

- GAVI has a number of its own internal windows HSS, new vaccines, ISS, CSOs it would be good if GAVI would develop its own internal common platform. More clarity is urgently needed for example on the future of GAVI's own HSS window, as well as ISS. At this point, GAVI needs to make decisions in principle so that the practical recommendations regarding GAVI's future support to health systems can be developed.
- While the paper developed by the High Level Task Force on International Financing for Health identified 49 GAVI-eligible countries, as eligible for HSS support, clarification is needed as to whether all GAVI-eligible countries would be able to apply for support under the joint platform
- Future support for health systems needs to place a stronger emphasis on the role of civil society. Concerns were voiced that the joint platform might be too public sector focused, and that funding would be primarily directed to the public sector. It was clarified that the process is meant to be fully inclusive, and the Board paper will seek to flesh this out in more detail.
- It was clarified that alternative 1 would include a joint planning process but would maintain a specific proposal and Geneva-based review process. Alternative 2 encompasses a joint plan and a joint assessment process, moving away from the Geneva-based IRC (GAVI) and TRP (GFATM) approaches. Alternative 2 is considered the 'best case scenario' and the direction GAVI would ultimately like to take.

The Committee agreed to recommend to the Board that the HSS joint platform should include the following components:

- a) Both alternatives should be pursued with countries able to decide which alternative would work for them. For example, some countries may be ready for alternative 2 while others may opt for alternative 1 because their internal systems are not yet sufficiently harmonised.
- b) Recommends a pilot approach that should be demand led, and country driven. It should be linked to a close monitoring and review process so that lessons learned and outstanding operational issues can be assessed.
- c) Close collaboration with the other partners
- d) The paper needs to clarify the working definition of health systems support; the WHO 'building blocks' are currently being used.
- e) The joint HSS platform needs to have a strong performance-based approach taking care of both the health systems results as well as links to immunisation performance (output and outcome). However, performance based is itself open to different definitions and achieving agreed actions and intermediate steps would also need to be considered as part of "results." An interagency committee has been established for the purpose and will be meeting in October. The group is closely linked with the IHP monitoring and evaluation efforts.
- f) The proposal to the Board should incorporate findings from the various evaluation and other exercises (the independent HSS evaluation, the tracking study, the IRC reports, the HSS Task Team 'lessons learned' etc).

4. WHO and UNICEF 2010 Work Plan Activities

GAVI Senior Programme Officer, Pooja Mall updated the Committee on the status of the 26 activities being conducted by UNICEF and WHO for which the Board delegated to the PPC¹ decision-making authority on future funding. **Brief discussion followed:**

¹ November 2008

- PPC members were satisfied with the level of reporting, including the justifications for the delays in progress on certain activities.
- The 2011-2015 GAVI Alliance Strategy Agreed should strongly consider issues of what it means to be an alliance and whether GAVI should be funding WHO, UNICEF and World Bank 'core mandate' activities.

Decision:

The Programme and Policy Committee:

1. **<u>Approved</u>** disbursement of 2010 funding for the UNICEF and WHO activities presented (\$11,072,360 of which \$7,969,360 for WHO and 3,103,000 for UNICEF).

5. Committee self assessment

[Summary of discussion to be provided by Egon Zehnder]

6. GAVI Long Range Forecasting and Impact Model

GAVI Senior Policy Programme Manager Gian Gandhi briefed the Committee on the ongoing work to develop a robust impact model for GAVI. **Brief discussion followed:**

- The PPC took note of the work done so far and agreed that communication about the model, its underlying assumptions and its results will be critical. The model may have policy related consequences that need to be brought back to the PPC in a timely manner.
- Critical parameters of the model are undergoing comprehensive analysis and validation by the US Centers for Disease Control (CDC); i.e. the disease impact metrics: lives saved per 1,000 vaccinated; and cases averted per 1,000 vaccinated.
- It was agreed that the model should strive to use 'gold standard' outcome measures such as DALYs as and when they are available for all diseases measured. However, since cases and deaths averted are more comprehensible to the lay audience than DALYs and because they are necessary to calculate DALYs, all three outcome measures should be presented when there is sufficient information available to do so.
- The comprehensive review and revision of the model is currently in progress and upon completion can be shared with a broader audience. However, recognizing the sensitive and confidential nature of some of the input variables (e.g. price projections, country specific demand forecasts) some of the inputs will need to be "locked", "hidden" or removed.

7. Resource Allocation / Prioritisation

GAVI Managing Director for Policy and Performance, Nina Schwalbe and GAVI Senior Policy Programme Manager, Gian Gandhi presented to the Committee potential methods for prioritisation and resource allocation. **Discussion** followed:

- As the majority of GAVI resources are allocated to vaccines and country programmes to deliver these vaccines, the prioritisation discussion focused on these activities, but recognized that GAVI should review other areas as well (i.e. workplan, administration).
- Prioritisation is clear complement to the eligibility work. The PPC agreed that eligibility should be broad; whereas prioritisation should be a tool to allocate resources if adequate resources to support all eligible applications were not available.
- While the Board had identified some key principles to guide the prioritisation exercise at its retreat in Rotterdam in March, PPC members felt that all twelve GAVI programme principles should be considered in the prioritisation exercise.
- Committee members agreed that existing commitments are firm GAVI must stand behind the legally binding and 'moral' commitments it has already made to currently eligible countries to support their programmes through 2015.
- Completing introduction of Hib pentavalent vaccine in all GAVI countries should remain the next priority.
- The focus for discussion of prioritisation should be the newer vaccines and country applications for these meningitis, pneumococcal and rotavirus and future vaccines HPV, JE, rubella and typhoid. This question could also be articulated in the context of the new strategy.
- GAVI needs to think clearly through when support would end (i.e. when does GAVI end support for penta?). This should be followed up in the context of the graduation and co-financing policy revision and perhaps addressed in GAVI's work to define, create and sustain healthy vaccine markets during 2010.
- GAVI will need to decide whether to take a sequential or more targeted approach to these vaccines offer countries one or a small number of vaccines, and once these vaccines are 'globally' introduced (i.e. across the majority of GAVI eligible countries), GAVI would make the next vaccine(s) available. Alternatively, GAVI could adopt a 'menu'-based approach allowing countries to apply for any one of the vaccines that GAVI funds at any time in line with relevant filters for prioritization/resource allocation. Issues of market impact, epidemiology, and country ownership can be argued for each approach. As part of the 2010 work to be undertaken by the Secretariat on Healthy Markets, both options should be further explored to understand potential impact on vaccine markets and pricing.
- In addition, GAVI will need to develop a transparent mechanism for prioritising new approved applications for GAVI support such that it can prioritise between countries in the instance that mobilised resources are insufficient to fund all IRC approved applications.
- In the best case scenario prioritisation decisions would not need to be employed at all. However it will become clear in the next few months whether this will be necessary as the resource mobilisation efforts begin to shed light on available resources.
- In the meantime, it would be prudent for the Secretariat to develop an approach for prioritisation that both encompasses prioritisation by vaccines (i.e. sequential introduction versus a menu of options) and prioritisation by country for newly approved applications.
- One option that was mentioned but not discussed in detail was the delaying of application rounds. This is something that the Global Fund sometimes does to provide additional time to further mobilise resources. As such, GAVI could consider delaying the next round(s) of new IRC applications. GAVI will need to assess the implications of delaying application rounds.

Taking into account the guidance provided by the PPC, the secretariat will continue working on principles for prioritization to be presented to the Board in November. This will be followed by

work with WHO, UNICEF and other partners on the development of specific criteria for resource allocation.

8. Vaccine Investment Strategy Implementation Plan

(Vaccine industry representatives were asked by the Chair to leave the room for reasons of conflict of interest.)

GAVI Managing Director for Policy and Performance Nina Schwalbe presented to the Committee options for implementing the new vaccine investment strategy. **Discussion followed:**

- In the interests of fiscal prudence, the Secretariat presented options to move forward with a subset of four vaccines identified (typhoid, rubella, HPV, JE) as part of last year's investment strategy deliberations
- However, the PPC recommended the Secretariat to move ahead with the preparatory activities as described in the paper.
- It is difficult to make a decision on whether to recommend that the Board should open a new funding window without understanding the magnitude of what seem like favourable resource mobilisation opportunities associated with the respective vaccines (e.g. HPV provides a significant opportunity to engage cancer and reproductive health constituencies while JE offers an opportunity to engage donors whose interested are more aligned with the south-east asian JE endemic region).
- While GAVI will only accept earmarked funds under exceptional circumstances, as described above, there may be increased donor interest in supporting GAVI should GAVI decide to offer countries HPV vaccine.
- The background paper proposed that under the AVI framework a group could be constituted to look more closely at typhoid vaccines, consider the strategies and monitor the development of the conjugate vaccine in close collaboration with the WHO prequalification group and the SAGE. The Gates foundation offered to serve as the lead on convening such a group.

The PPC recommended:

- Given the current financial climate, the Secretariat should develop country application guidelines for HPV, JE and rubella for each of the new vaccines.
- These should then be brought to the Board for approval in 2010 along with further characterization of the potential available resources and in the context of GAVI's new strategy for 2011-2015 and the results of the prioritization exercise
- With regard to typhoid, the Secretariat should work closely with the Gates foundation as they convene a group to consider potential strategies and monitor development of the conjugate vaccine.

9. In-Kind Donation Policy

GAVI Senior Policy Manager, Gian Gandhi briefed the Committee on the revision of the In-Kind Donation Policy that GAVI had completed to address previous comments received from the PPC on the policy revision. The PPC decided to make the following recommendations to the Board:

GAVI does not accept In-kind donations of vaccines except for in exceptional cases:

The following cases may be considered and possibly accepted:

- i. For stockpiles to address emergency outbreaks in exceptional circumstances, when another institution cannot accept the donation
- ii. In a situation where GAVI faces a severe supply shortage due to problems with allocated supply (e.g. due to batch contamination,)
- iii. When, in the absence of the donation, GAVI would have funded the procurement of the vaccine on behalf of a country from the specific manufacturer that is now donating vaccines

If GAVI does in the above mentioned exceptional cases accept in-kind donations of vaccines, it does so with the following conditions:

- i. Donations comply with UNICEF/WHO Vaccine Donations Guidelines
- ii. Countries which receive donations of vaccines that they would otherwise receive support for through GAVI, must still pay co-financing in line with the current GAVI co-financing policies
- iii. Donation of vaccines for routine use should in principle, be equivalent to at least one full year's provision (at current levels of coverage plus buffer, stock as necessary) for a country

In-kind donations of other health products will <u>not</u> be considered due to the transactional costs of taking a case-by-case approach.

10. Any Other Business

- The issue of whether or not GAVI allows countries to procure non-WHO prequalified vaccines using GAVI funding was raised. The Secretariat, in collaboration with WHO and UNICEF, will present a paper on this for the next PPC meeting.
- Members of the PPC asked about GAVI engagement in a new Merck Welcome Trust collaboration for vaccine development. GAVI is not formally a partner in the venture however the Secretariat attended a brainstorm meeting in January and will send information received to date to interested PPC members.
- The PPC asked for update on resource mobilisation at the November Board, including how the board member advocacy plan is progressing.
- PPC members requested regular updates on the AVI. It was noted that information had been included in the materials sent out in advance of the meeting. Members were thus asked to advise the Secretariat about the kind of information required. The PPC asked that any updates that are provided regularly to Board members be provided to the PPC members as well.
- The conflict of interest policy should be universally applied. For example, it was noted that just as industry was asked to leave the room during the vaccine investment strategy discussion, WHO and UNICEF should have left the room during decisions on the work plan.
- In setting the governance calendar for 2010 the Secretariat needs to consider the role of the PPC in work plan development and input into the strategy.
- Moving forward, country support updates will be provided regularly to the PPC including IRC policy recommendations.
- As a follow-up of the self.-evaluation, the PPC went through its Charter and discussed the duties included and suggestions for other inclusions. It was recognised that several issues need to be pursued in a better way (see previous point). Furthermore it was suggested that the draft agenda

for the PPC meetings be shared with the members of the PPC. Suggestion for inclusion in the agenda is welcome, but needs to be in time for proper secretariat preparation if such is needed. It was further advised that the PPC meeting papers be distributed 14 days before the meeting to facilitate broad consultation within constituencies. The issue of constituency representation was raised. The committee is only a few people being short of representing all constituencies in the board and therefore a large committee without having the advantage of being a "committee of the whole". Although it may be too difficult to transform the PPC into a "committee of the whole" in which all Board seats are represented, it may be done by constituencies agreeing on a person representing several "likeminded" constituencies. This would strengthen the outcome of the discussions of the PPC and make the board meetings and the entire governing structure more effective.

• The chair thanked the Secretariat for the good and thorough preparatory work that facilitated the PPC discussions and decisions