13th GAVI BOARD MEETING

Washington, DC, 6-7 July 2004

FINAL SUMMARY REPORT

1 GAVI Progress Report

- The activities set out in GAVI Work Plan 2004-05 are on track for the most part, after some initial delays in a few areas due to financial bottlenecks.
- The progress of GAVI needs to be considered within a context of expectations to know what
 goals are being set, what has been done to reach those goals, and how the progress measures
 gainst these goals.

DECISIONS

The Board:

- 1.1 Requested the President of The Vaccine Fund to provide an in-depth presentation at the next Board meeting on its financial situation.
- 1.2 Welcomed the offer by WHO to report back to the EC at its next meeting on the status of the Vaccine Provision Project.
- 1.3 Welcomed the development of a global immunization strategy being prepared by UNICEF and WHO in consultation with the wider community, and suggested that the new director of WHO Immunization, Vaccines and Biologicals department (IVB) make a presentation on the progress of the strategy development at the next Board meeting

2 Recommendations of the Independent Review Committee

- It will be important to look into the reasons why a substantial portion of immunization services support (ISS) funding has not been spent. [The Secretariat is preparing a more in-depth analysis which it will provide to the Board as soon as possible.]
- As the IRC monitoring team has just finished its most recent review, the official report of the team, including its policy recommendations, will be presented formally to the GAVI Executive Committee for discussion and decision shortly. [Done on 15 July]

DECISIONS

The Board:

- 2.1 Agreed to recommend to The Vaccine Fund to release US\$ 4,887,500 to fund the proposals recommended for approval by the Independent Review Committee's (IRC) review team.
- 2.2 Decided to consider how to support low income countries under stress at a future meeting.

3 The GAVI long-term strategy

GAVI is strong because of its convening power and the complementary roles of all the partners
 most of whom have been involved in immunization for a long time. On the other hand, much

- of the real power behind the alliance is the resources of the Vaccine Fund a new source of funding that the GAVI Board must ensure is additional and spent in the most optimal way.
- The dual nature of GAVI creates difficulty in identifying its true value and role. GAVI as an
 alliance has adopted very broad goals related to the entire global immunization arena. The
 resources in The Vaccine Fund, however, have been used for very specific purposes. Looking to
 the future, it will be critical to develop and use simple messages that describe the dual nature of
 GAVI in clear terms.
- The need for clarity in describing the role of the Vaccine Fund will be especially critical for fundraising activities; the financing requirements of the Vaccine Fund must be put into the context of the global financing requirements for immunization so that its particular added value can be recognized and financing needs of partners can be supported.

The Board:

- 3.1 Endorsed the outcome of the EC retreat discussions on GAVI's long-term strategy but requested further work be done to clarify:
 - 3.1.1 The principles, criteria and strategic priorities for the use of Vaccine Fund resources by simplifying the language, reducing the number of items to only the most salient points, and better distinguishing the difference between principles and criteria in the decision-making process.
 - 3.1.2 That time-limited does not mean short-term.
 - 3.1.3 The concept of sustainability.
 - 3.1.4 That the resources of The Vaccine Fund are complementary, building on and supporting what the partners are doing.
 - 3.1.5 That funding to low income countries under stress should continue to be flexible, with channelling through partners as necessary.
 - 3.1.6 How the convergence of the GAVI Secretariat and The Vaccine Fund will affect the messages about GAVI's long-term strategy.
- 3.2 Agreed that it will need to consider whether to change its mission statement and objectives in light of the agreement on the further clarification of the role of GAVI and The Vaccine Fund.
- 3.3 Requested the coordinating group on global advocacy to take responsibility for coordinating and improving messaging on GAVI's long-term strategy and dual role, in an iterative process that builds on the discussions and recommendations of the sub-group of the GAVI Board on governance, the WHO/UNICEF global strategy, and other relevant processes as they develop.

4 Financing

- Increasing the resources available for health from developing country government budgets is as important as increasing overseas development aid.
- The Board welcomed the development of common analyses of the funding gap for reaching immunization-related MDGs. These analyses will be formulated through the IFF planning process (see below) and the WHO/UNICEF global immunization strategy consultative process.
- Fundraising activities will be more effective if partners are consistent in what they say about these strategies and resource needs, and the specific roles of The Vaccine Fund and different

partners in the global effort. Messaging needs to be developed as part of the work being undertaken by the coordinating group on global advocacy.

5 International Finance Facility

- If the IFF for immunization goes forward, it will be in effect a launch of the IFF concept, on a limited scale.
- Immunization is a promising area in which to test the concept of the IFF, but many more details are needed, including criteria for funding, disbursement mechanisms, and the financial architecture. There are many assumptions, such as future reductions in vaccine prices and absorption capacity of poor countries; these assumptions require validation.
- The Board will need to know the pros and cons of the mechanism and the potential risks of creating a link to GAVI. The World Bank autumn meetings might provide a good opportunity to gain this knowledge.
- Care must be taken so that an IFF for immunization does not make distortions; with each new vehicle comes the risk of more fragmentation.
- It is not yet clear how the money raised by the immunization IFF would be disbursed these issues are under discussion.

DECISIONS

The Board:

- 5.1 Applauded the leadership of the UK government in designing and proposing the IFF; if the IFF materializes it could have a profound effect on development.
- 5.2 Endorsed further exploration of the IFF for immunization by the 'trio plus two': WHO, UNICEF and The Vaccine Fund, plus the World Bank and the Gates Foundation.
- 5.3 Requested simple, straightforward briefing materials as soon as possible, by the GAVI partners. Advocacy materials should be developed after Board agreement had been reached on an IFF for immunization- project.
- 5.4 Agreed to continue discussing the IFF for immunization with interested donors.
- 5.5 Requested the GAVI EC to have a comprehensive discussion of the immunization IFF at its next meeting.

6 Measles Investment Case

- The document provided as an addendum to the original measles investment case addresses the concerns raised by the Board.
- Channeling some of the \$50 million through the GAVI/Vaccine Fund country support
 mechanism would result in a \$3 million loss in matching grants from the UN Foundation.
 However, upholding the GAVI emphasis on bottom-up country application processes would be
 worth the reduced financial contribution.

DECISIONS

The Board:

6.1 Approved option B outlined in the addendum of the measles investment case, namely:

- 6.1.1 The Vaccine Fund will contribute \$37 million to the UN Foundation for "catch-up" campaigns. This will trigger a \$9.25 million matching grant from the UN Foundation. The relevant countries will access resources for catch-up campaigns through the Measles Partnership.
- 6.1.2 The Vaccine Fund will make available \$13 million to support implementation of a routine second dose of measles vaccine in selected countries. The relevant countries will access resources for routine second measles dose through GAVI/Vaccine Fund country application mechanism.

7 EC retreat recommendations on optimal structures and process for GAVI & The Vaccine Fund

- According to the analysis conducted by the Center for Applied Research (CFAR), the financial
 benefits of convergence would not by themselves justify the move. However, the GAVI EC
 recommended moving forward on convergence for strategic reasons improving the
 performance of the Vaccine Fund and the GAVI Secretariat in supporting the needs of the
 partners in the alliance. Since the financial costs of convergence are within reason, the strategic
 justification remains.
- The Chair of the Vaccine Fund Executive Committee confirmed that it supports the convergence of the Vaccine Fund management and the GAVI Secretariat.
- At this time it does not make sense to consider merging the two Boards, for legal reasons. This may be considered at a future time.
- A top priority for the transition teams (see decision 7.2) will be to define the roles and responsibilities of the converged organization.

DECISIONS

The Board:

- 7.1 Agreed to the 'base case' for convergence described by CFAR, namely:
 - The GAVI Secretariat and Vaccine Fund management structure share common premises
 - o The common premises will be located in Geneva
 - Vaccine Fund staff members located in Washington, DC will remain in Washington, DC
 - o Both staff organizations report to a single leader
 - Vaccine Fund employees will remain employees of the Vaccine Fund (a private organization) and Secretariat employees will remain employees of UNICEF
 - The entities retain separate boards
 - Staffing levels will be based on the assumption that the Secretariat and Vaccine Fund carry out functions consistent with the roles described in the EC retreat report.
- 7.2 Requested two transition teams to carry out the necessary work one comprised of Board members and one comprised of GAVI Secretariat and Vaccine Fund staff.
- 7.3 Agreed that the staff transition team would be comprised of Bo Stenson of the GAVI Secretariat and Fabian McKinnon of the Vaccine Fund, and would be led by an independent consultant. This consultant would serve as a neutral party in the efforts and provide the considerable staff time necessary to conduct the work required of the transition. Once a new GAVI Executive Secretary is recruited, that person would take over the responsibilities of leading the staff transition team. The staff transition

team will review and formulate recommendations to the GAVI and Vaccine Fund Boards on substantive policy issues including, but not limited to:

- Legal issues, including status of staff and implications under UN regulations
- Organization design and staffing, including an ideal design of the converged entity and staff roles and responsibilities
- Messaging, including messaging about the converged entity in light of the overall strategy
- Human resource and operating policies
- Systems and infrastructure of the converged entity
- o Management of the legal and HR issues of separation and relocation
- Workplan and budget for transition
- 7.4 Agreed that the Board transition team would be comprised of Pascal Villeneuve of UNICEF and David Fleming or Sylvia Mathews of the Gates Foundation, and be chaired by Chip Lyons, Chair of the Vaccine Fund Executive Committee. The Board transition team will review and formulate recommendations to the GAVI and Vaccine Fund Boards on substantive policy issues including, but not limited to:
 - o Roles and responsibilities of the converged entity
 - o Legal issues oversight
 - o Configuration of the Boards and their coordination
 - Oversight of the staff transition team
- 7.5 Requested both the transition teams to report back to the GAVI EC by September or October. The staff transition team will report to the Board transition team as needed.

8 Investment Case Framework

- The process outlined in the investment case framework is designed to help the GAVI Board make global decisions about where GAVI will invest the resources of the Vaccine Fund in the next phase of GAVI. The framework will come into use once the Board has made the necessary strategic decisions about the long-term goals of the alliance. These long-term goals will be heavily informed by the Global Immunization Strategy currently being developed by UNICEF and WHO in consultation with the broader immunization and health community.
- The investment case framework is not intended to be used by countries that will request new types of support from the Vaccine Fund in the next phase of GAVI. Country support requests will be managed through a modified version of the current country support process.
- The investment case framework describes a complex decision-making process. Some Board members felt this complexity is warranted, considering the large financial implications of these decisions; other Board members felt a more simple route would be preferred; others were concerned that the role of recipient countries in deciding priority investment is not apparent.
- Most Board members felt that the proposed two-step process of initially inviting and reviewing letters of intent and subsequently requesting full investment cases is not required. Instead, the Working Group could vet ideas for new investment cases.
- The proposal to provide up to \$50,000 in seed money to an organization or group of partners developing an investment case, was positively received, as long as the number of investment cases is limited and the investment cases are actually solicited by the Board.
- No consensus was reached regarding whether to create a separate review mechanism to make recommendations to the GAVI Board regarding investment cases, or to use existing mechanisms such as the GAVI EC or the Working Group.

The Board:

8.1 Requested revision of the investment case framework to simplify and streamline the proposal, before it could be approved for use. The Secretariat will work with the World Bank team to provide a revised proposal to the Board at its next teleconference.

9 EC retreat recommendations on long-term vaccine availability and affordability

• This issues of long-term vaccine availability and affordability are especially pertinent to the discussions on Hib vaccine uptake and the GSK rotavirus vaccine which will soon be available.

DECISIONS

The Board:

9.1 Agreed that UNICEF and the Gates Foundation should convene a small steering group to elicit suggestions from the EC and design a process to review and address procurement concerns.

10 Hib update

- There are significant challenges in securing the long-term supply of Hib-containing pentavalent combination vaccines. Currently, 13 million doses of pentavalent vaccine are procured annually. This does not represent a significant market to vaccine manufacturers; market competition and price reductions will only come if demand increases.
- The Hib situation will reflect perception of success or failure of GAVI. Strategic supply and procurement approaches are important to develop.
- The dual objectives of affordability, and ensuring that the market is attractive enough for additional producers to invest in vaccine development, must be balanced.
- There is a dearth of disease burden information in developing country settings. In addition, some of the available data are inconsistent. Better collaboration with other pneumonia and meningitis surveillance efforts, such as those being undertaken by the pneumoADIP, could improve the information situation.
- Given the many programmatic and operational challenges surrounding the introduction of Hib
 vaccine it is paramount to involve countries in the development of any revised GAVI Hib
 strategy.

DECISIONS

The Board:

10.1 Agreed to constitute an ad hoc group representing skills and expertise in programmatic, financing, procurement and supplies with representatives from country and global levels. The proposed list of participants (attached) was approved with the addition of the Board members from research institute (Holmgren) and from the technical health institute (King).

10.2 The team will undertake a broader situation analysis and present a report on country information needs and key issues for updating the GAVI global Hib strategy within the next three to four months.

11 Proposal for bridge financing

- While the proposal does have merits, many Board members raised questions about the reliability of the projections concerning potential 'mature prices' for the vaccines.
- The GAVI Board could consider advocacy efforts targeted at encouraging the 90 developing to
 middle income countries not eligible for Vaccine Fund support to introduce the new vaccines, in
 an effort to increase the size of the market.
- As new vaccines enter the market it is a given that vaccine prices will be higher than the older,
 off-patent vaccines that formed the foundation of the EPI programme. It will be necessary to
 accept the fact that even at higher prices, these vaccines are among the most cost-effective health
 interventions.

DECISIONS

The Board:

- 11.1 Agreed to pursue the principle of cost-sharing with countries that are now receiving combination vaccines, after the first five years of support.
- 11.2 Requested more analysis on options for level of co-payment offered to countries in addition to 'mature price' and more consultations with countries and donors, before the proposed direction outlined in the paper can be endorsed. The Financing Task Force, supported by the World Bank, will work with the GAVI Working Group, as appropriate, to develop the revised proposal.

12 Report of the ADIP Management Committee

- The ADIP Management Committee has reviewed and endorsed the progress of both the Rotavirus and Pneumococcal ADIPs.
- The rapid progress of the new rotavirus vaccines are an exciting development with attention of the two lead companies being focused on the needs of both the developed and developing world. Glaxo Smithkline (GSK) is planning to launch its product first in middle income countries prior to introduction in Europe. Merck & Co, plans to file its product simultaneously in the developed and middle income countries.
- The Rotavirus ADIP is working with both companies to conduct studies in developing countries, where rotavirus diarrhea has a high mortality/morbidity, as it is uncertain how either product will perform in Vaccine Fund eligible countries.
- Considering the experience with Hib, reliable disease burden data must be available before considering widespread introduction of rotavirus vaccines in Vaccine Fund eligible countries.
- WHO is in contact with the Mexican national regulatory authority (NRA) about moving ahead on the pre-qualification process of the NRA, a step needed for the NRA to function as a reference authority. The timeline for the process is unclear.
- Regina Rabinovitch will from now on represent the Gates Foundation on the ADIP Management committee, replacing Rick Klausner.

The Board:

- 12.1 Endorsed the report of the meeting and the progress of the Rotavirus and Pneumococcal ADIPs
- 12.2 Requested the Rotavirus ADIP to explore opportunities to participate in testing and pilot introduction of the rotavirus vaccine candidates to, (1) develop necessary data for support of widespread introduction in developing countries including Vaccine Fund eligible countries and (2) address issues of strategic importance to GAVI & The Vaccine Fund such as assessing the feasibility of the vaccine's introduction in poor countries with weak health infrastructure.
- 12.3 Agreed to establish a small, time-limited group to explore with GSK and Merck (at this stage) the technical, scientific and cost characteristics required for early introduction of rotavirus vaccines in Vaccine Fund eligible countries. Price/volume negotiations would then be conducted with the companies.
 - 12.3.1The composition of the group is: John Wecker, Rotavirus ADIP Exec. Dir.; Orin Levine, Pneumococcal ADIP Exec. Dir.; Jan Holmgren, Chair of ADIP Mgmt Comm; Kevin Reilly, Member Mgmt Comm; Regina Rabinovich, Gates Foundation; Steve Jarrett, UNICEF Supply Division; Jacques-Francois Martin, The Vaccine Fund, Marie-Paule Kieny, WHO, and Tore Godal, GAVI Secretariat.
 - 12.3.2The group will need to begin work immediately; its terms of reference will be shared with the Executive Committee and the Board.
 - 12.3.3The Group will report through the ADIP Management Committee to the full Board at its next meeting.
- 12.4 Requested UNICEF to clarify why it has not yet signed the Memorandum of Understanding (MOU) with the Rotavirus ADIP at PATH. The UNICEF representative promised to provide the Board with a written update by email, as the information was not available at the time.

13 Preliminary findings of the evaluation of GAVI immunization services support (ISS)

- The initial analysis was interesting but it will be important to conduct further analysis into the system and its impact. For instance, it might be instructive to look for differences in district-level coverage within countries.
- It is nearly impossible to attribute changes in basic immunization coverage rates to a single cause, considering the interdependency of the health system.
- Some Board members felt that even though the principle of the ISS system is to provide flexible funding it would be helpful if GAVI were to provide countries some guidelines about best use of funds.

14 Improving the country application process and time-limited extension of ISS funding

 The Board could not reach consensus on whether to approve a time-limited extension of ISS funding. Some Board members questioned whether ISS funding fulfills the Vaccine Fund principle of providing a 'step change' to immunization programmes. Further analysis was requested.

The Board:

14.1 Agreed that the Secretariat and the Working Group should continue working on the design of country application process for the second phase of GAVI according to the directions outlined in the document.

15 Proposed review of GAVI governance processes

DECISIONS

The Board:

- 15.1 Approved the draft terms of reference for the review, with a longer timeframe the group should report to the Board at its next meeting in December, not before, to allow the necessary consultation and finalization of the recommendations.
- 15.2 Approved the composition of the group. Chair: John Lambert, Chiron. Members: Joy Phumaphi, WHO; Bruno Floury, France; Professor Nymadawa, Mongolia; Sigrun Mogedal, Norway.

16 Yellow fever stockpile

DECISIONS

The Board:

- 16.1 Endorsed the annual progress report for the yellow fever stockpile.
- 16.2 Requested the Vaccine Fund to release a *maximum* of \$6 million for the 2005 supply. The Vaccine Fund will need to make the final financial decision, depending on the outcome of the final negotiations between UNICEF Supply Division and the manufacturer.

17 2005 Budget for Vaccine Fund Trust Account at UNICEF

DECISIONS

The Board:

17.1 Approved the proposed 'bridge' budget in the amount of US\$ 3,592,347 for UNICEF for administration costs in 2005 related to the management of the Vaccine Fund Trust Account at UNICEF and the procurement of vaccine on behalf of the alliance.

18 Next Board, EC meetings

- The next Board meeting will be in Abuja, Nigeria on 4-5 December (Saturday, Sunday), to be convenient with the High Level Forum on Health being held in Abuja on 2-3 December. Board members are advised to make travel plans soon.
- The next EC meeting will be in early November.

ATTACHMENT

Members of GAVI Hib Team

Name		Institution	Area of Specialty
1	. David Fleming (Chair)	Gates Foundation	Public Health
2	. George Amofah	Ghana Health Service	Health system financing
3	. Issa Makumbi	Uganda EPI	Country programmatic experience
4	. Patrick Zuber	WHO	Epidemiology (disease burden)
5	. Dr Endang	Independent Consultant, Indonesia	Epidemiology
6	. Stephen Jarrett	UNICEF	Vaccine Procurement
7	. Dr. Pascal Perrin	Aventis	Vaccine manufacturing
8	. Steve Landry	Vaccine Fund	Vaccine financing
9	. Piers Whitehead	Participating based on former work with Mercer Consulting	Economics of vaccine supply
1	0. Damien Walker	LSTMH	Cost effectiveness studies
1	1. Orin Levine	Pneumo ADIP	
1	2. Jan Holmgren	Gothenberg University	Research institute
1	3. Shelley Deeks	Health Canada	Technical health institute

Coordination – Mercy Ahun, GAVI Secretariat, Country Review & Progress including financial commitments