

# Global Alliance for Vaccines and Immunization

**Third Board Meeting**

**Oslo, Norway, 13-14 June 2000**

**GAVI** Global Alliance for  
Vaccines and Immunization

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# Executive summary

## 1. Introduction

The Norwegian Minister of International Development, Anne Kristin Sydnes, welcomed the GAVI Board to Norway, emphasizing the importance that the Norwegian government attaches to GAVI because of the promise that it holds as an innovation in international development. She encouraged all participants to take active part in the symposium to be held in the afternoon, at which Prime Minister Jens Stoltenberg would make the welcoming address (See Annex 1 for annotated agenda, the Chair's summary, and Stoltenberg's speech).

Dr Gro Harlem Brundtland, Director-General of WHO and Chair of the GAVI Board, introduced the topics for discussion over the two-day meeting (Agenda attached), and grouped them into three themes:

- Making a difference on the ground, quickly (country proposals, vaccine procurement, management relating to Global Fund).
- Strengthening and expanding the GAVI partnership (polio eradication, basic principles for GAVI structures, Partners' meeting).
- Looking to the future (sustainable financing, research and development).

## 2. Country proposal update and review process

The Board approved basic principles of the review process (see Annex 2), recognizing the importance of responding to countries' needs and situations. The Board:

- Adopted measures to avoid conflicts of interest, acknowledging the necessity of including representatives of eligible countries on the independent review committee.
- Recommended that GAVI explore participation of representatives from Eastern and Central Europe on the committee.
- Commended efforts to date to explore special arrangements to address the needs of the largest countries, and emphasized the need to secure more resources to "immunize every child".
- Endorsed the need to rapidly expand the number of trained staff at country level (with immunization as well as health systems related skills), that would be funded by partner support through the lead agencies (WHO, UNICEF).

As the operations of GAVI move to on-the-ground efforts, the Board advised the Advocacy Task Force to focus on developing country activities.

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### 3. GAVI and the Polio Eradication Initiative

Considering the links between the GAVI and the polio eradication goals and objectives (see Annex 3), the Board:

- Requested that the GAVI Working Group and the core polio eradication group work closely together to develop practical and concrete strategies for strengthening the collaboration on a country-by-country basis.
- Acknowledged that in two to three years' time, as human and capital requirements for the polio eradication effort decline, partners must take on the leadership and advocacy challenge to redirect the newly-freed financial and human resources to address the GAVI objectives.

### 4. Financing Issues

#### 4a) *Vaccine Procurement Strategy*

The vaccine procurement strategy has been designed by UNICEF to capture the best and most current technologies that will facilitate access and increase safety, with a specific focus on the needs of the poorest countries (see Annex 4.1a). In this context, the Board:

- Strongly endorsed the delivery of vaccine combinations.
- Adopted the proposed innovative vaccine procurement strategy that engages the commitment of industry to the global goals of GAVI and provides a reliable and predictable procurement process. Increased attention is given to the needs of industry for longer-term planning, based on a competitive request-for-proposal approach.
- Endorsed the proposed timeframe for procurement, including the target of product acquisition by the end of November 2000 appreciating the time constraints.
- Expressed its gratitude to vaccine producers for donating vaccines to GAVI and adopted a vaccine donation policy (see Annex 4.1b).
- Discussed policy challenges related to tiered pricing in the developed countries, especially in the United States.
- Recognized that UNICEF is responsible for the implementation of vaccines procurement financed through the Fund.
- Recommended that the GAVI Financing Task Force continue to support the procurement policy development by:
  - developing guidance for countries to use in selecting vaccines and vaccine presentation (WHO lead);
  - improving the process of demand forecasting including planning for new vaccine presentations;
  - determining the potential impacts of limited capacity technologies such as lyophilization.

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#### **4b) Sustainable Financing**

Board members from developing countries emphasized the importance of building national commitment from year one of Fund disbursements (see Annex 4.2). Recognizing the difficulty of ensuring and measuring national commitment, the Board:

- Emphasized the central role of national governments and endorsed the concept of engaging the Ministry of Finance in the development of long-term plans for financial sustainability of immunization programmes, recognizing that the World Bank has a primary responsibility to secure appropriate links with ministers of finance.
- Endorsed the proposal to extend Fund resources beyond five years by a phased transition of support. This would provide greater incentives for countries to obtain support for immunization from other sources, including national governments, bank loans and bilateral funding.

Following the discussions of the donors to the International Development Association (IDA), the World Bank has committed to initially make US\$ 1 billion in IDA resources available for communicable disease control programmes, and has announced its intention to move well beyond that level in the future as national and regional programmes are developed. IDA financial and technical resources are a critical complement to the resources of other GAVI partners and the Fund to build national commitment, immunization capacity and ensure sustainable financing and access to immunization with current and future vaccines.

The World Bank is committed to better design of projects, including immunization, to meet the needs of the social sectors. This requires harmonization of activities at country levels including common approaches to assessment and outcomes measures.

The GAVI Board strongly endorsed the World Bank initiative to expand its support for communicable diseases through immunization and other cost-effective strategies.

WHO committed to promote the use of IDA loans for health at the country level, and to work to elaborate on the cost and benefit terms of using loans, as opposed to grants, for immunization services.

#### **4c) Incentives for R&D commitment from industry – “pull” mechanisms**

The GAVI alliance has already adopted two key strategies to encourage increased commitment to vaccine research and development in industry, or “pull” mechanisms: the mobilization of partners and the Fund to strengthen immunization services in low-income countries, and the purchase and introduction of available under-used vaccines.

The Board requested that the Financing Task Force research and report back to the Board about the specific actions that the Board can take to create further incentives in the form of “pull” mechanisms (see Annex 4.3). Working with the Task Force on R&D where needed, the Financing Task Force was asked to identify:

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- Specific constraints of a few priority vaccine projects which can be overcome through Board actions.
  - Actions to promote the World Bank's communicable disease initiative with access to an initial US\$ 1 billion of IDA resources.
  - Pros and cons of the R&D window of the Global Fund being used as an additional pull mechanism.

In addition, the Board requested that the World Bank explore how IDA might provide a "pull" mechanism for the purchase of future products such as AIDS, malaria and TB vaccines.

## **5. Research and Development**

The Board gave its strong endorsement for the need of a GAVI Task Force on Research and Development and voiced its support for the work that has been done to date by the pre-task force (see Annex 5).

This task force will adopt a strategic approach in its advice to the Board, with activities to be implemented through existing partners.

The task force will have three co-chairs, representing academia, industry and WHO. The selection of other task force members will be decided by the co-chairs with the Executive Secretary. In order to secure coordination, the members should be drawn from existing committees and panels in the R&D field and include experts with broad expertise of the vaccine field. In order to be effective, the task force should be limited to a small number of members.

After members are selected, terms of reference including specific goals and specific areas of focus will be developed by the task force, in close consultation with scientific community, for endorsement by the Board at the November 2000 meeting.

The Board requested a strong role for WHO in the task force. WHO will ensure that the activity of the task force will not overlap with that of the WHO Strategic Advisory Group of Experts (SAGE).

The Board recognized that the specific mentions of the need for vaccines against HIV/AIDS, malaria and tuberculosis in the GAVI strategic objectives are cited examples of vaccines that are needed in developing countries. The Research and Development Task Force will also consider other disease areas and new technologies that would improve safety and performance.

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## **6. Global Fund Administration and Procedures**

### ***6a) Fund Update***

In his speech at the symposium, Norway Prime Minister Jens Stoltenberg announced a pledge from Norway to provide 1 billion kroner over five years to GAVI (approximately US\$ 25 million per year), as part of the government's strategy to promote stronger health systems in low-income countries.

The United Kingdom announced that it would be purchasing 250 000 shares in the Global Fund this year to vaccinate 250 000 additional children, at a value of £3 million (approximately US\$ 5 million). The Department for International Development (DFID) will be reviewing its budget with the possibility of providing additional resources to GAVI in the future.

In the initial stage of the Fund support process, countries which have relatively strong immunization systems and the infrastructure to absorb new funding will inevitably be best positioned to fulfil the requirements for Fund support to reach unimmunized children and introduce new and underused vaccines. It will be important for GAVI partners to actively address the needs of countries with weaker systems, including the poorest countries and countries experiencing political and social unrest, in order to ensure that all children have access to full immunization services.

The first two rounds of proposal reviews in 2000 will provide the critical experience necessary to determine the most effective means of reaching all eligible countries. The Task Force on Country Coordination will provide appropriate background information the Board at its next meeting, including an analysis of the situation in the 27 countries that have not yet indicated when they will be submitting proposals to GAVI. Specific strategies to reach out to countries with special requirements will be considered at the November Board meeting.

### ***6b) The Fund and the UNICEF Working Capital Account***

The funding needed by UNICEF to manage the increased workload related to the management of the resources from the Global Fund, which represents a nearly 25% increase in the funds normally managed by UNICEF, is slightly less than US\$ 2 million per year (see Annex 6). The UNICEF budget proposal was approved by the Board, provided that it undergo 'due diligence' through the GAVI Secretariat. Results of the due diligence will be forwarded to UNICEF, the GAVI Board and the Fund Board.

The Board requested a transparent outline of the Fund, its board, management and decision-making process, no later than August. The GAVI Working Group will provide the Board with this outline, including the relationship between the Global Fund and the Working Capital Account (term may change) at UNICEF. A teleconference will be scheduled to discuss the proposal with the Board.

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## 7. GAVI Structure and Management

### 7a) *Board Composition*

The Board decided to increase the number of Board members from 13 to 16 (15 + Chair) as follows (see Annex 7.1):

Renewable seats:

- The Bill & Melinda Gates Foundation
- UNICEF
- The World Bank
- WHO

Rotational seats:

- OECD country governments (3) – currently representatives of Canada and the Netherlands; one seat vacant.
- Developing country governments (2) – currently representatives of Bhutan and Zimbabwe, serving in their personal capacities.
- OECD country industry – currently Aventis Pasteur.
- Foundations – currently Rockefeller Foundation.
- Research and Development – currently US National Institutes of Health.
- Nongovernmental Organizations – currently PATH/CVP.
- Technical Health Institute – currently vacant.
- Developing country industry – currently vacant.

In addition, the Board decided to:

- Terminate the policy of alternates serving on the Board, i.e. if a Board member cannot attend the seat will be vacant.
- Institute a liberal policy for attendance by observers.
- Enhance communication about Board proceedings.

### 7b) *Guiding Principles*

The Board adopted the Guiding Principles outlining the roles and responsibilities of the different entities of the Alliance (see Annex 7.2a). It is likely that a slight revision to accommodate decisions made in the future about the relationship between the Global Fund and the Working Capital Account at UNICEF will be necessary.

The Board commended contributions made by regional staff to the GAVI process, including country support, and endorsed informal formations of regional partner groups to address specific concerns, such as the one developed in Africa (see Annex 7.2b).

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**7c) *Operations of the GAVI Secretariat***

The Board endorsed the document outlining the Operations of the GAVI Secretariat (see Annex 7.3), and suggested that it could be signed by the Chair of the GAVI Board and the Executive Director of the host Organization (UNICEF).

**8. Other matters**

The next Board meeting is 19 November in the Netherlands. The Board adopted the preliminary agenda (see Annex 8) for the Partners' meeting on 20–21 November following the Board meeting. The spring 2001 Board meeting will be held 20–21 June.

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# Adopted agenda

- 1. Welcome and Introductions**  
Gro Harlem Brundtland, Chair; Anne Kristin Sydnes, Norwegian Minister of International Development
- 2. Country proposal update and process**  
Michel Zaffran, WHO
- 3. Polio eradication and GAVI**  
Yves Bergevin, CIDA
- 4. Financing Issues**
  - a) Vaccine procurement  
Steve Landry, USAID; Steve Jarrett, UNICEF
  - b) Sustainable financing  
Chris Lovelace, World Bank
  - c) 'Pull' mechanisms  
Amie Batson, World Bank
- 5. GAVI R&D Task Force**  
Mike Levine, University of Maryland; Gus Nossal, University of Melbourne;  
John LaMontagne, NIAID
- 6. Global Fund Administration and Procedures**
  - a) Fund Update  
Mark Kane, Bill and Melinda Gates Children's Vaccine Program
  - b) Management of UNICEF working capital account  
David Alnwick, UNICEF
- 7. GAVI Structure and Management**
  - a) 'In Camera' session of the Board
  - b) Guiding Principles  
Tore Godal, GAVI Secretariat
  - c) Agreement between the Secretariat and the host institution (UNICEF)  
Umberto Cancellieri, GAVI Secretariat
- 8. Other matters**

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# List of annexes

<b>Annex 1.1</b>	<b>Symposium on poverty alleviation, health and vaccines .....</b>	<b>11</b>
<b>Annex 1.2</b>	<b>Symposium on poverty alleviation, health and vaccines .....</b>	<b>15</b>
<b>Annex 1.3</b>	<b>Speech of Prime Minister Jens Stoltenberg .....</b>	<b>17</b>
<b>Annex 2.1</b>	<b>Country proposal review process – basic principles .....</b>	<b>23</b>
<b>Annex 2.2</b>	<b>Estimated timing of submission of country proposals to GAVI .....</b>	<b>27</b>
<b>Annex 3:</b>	<b>GAVI and the Polio Eradication Initiative (PEI) .....</b>	<b>29</b>
<b>Annex 4.1a</b>	<b>UNICEF commitment to vaccine supply and the vaccine industry .....</b>	<b>31</b>
<b>Annex 4.1b</b>	<b>GAVI vaccine donation policy .....</b>	<b>35</b>
<b>Annex 4.2</b>	<b>Financial sustainability in year six and beyond .....</b>	<b>37</b>
<b>Annex 4.3</b>	<b>Incentives for accelerated R&amp;D for priority vaccines .....</b>	<b>41</b>
<b>Annex 5</b>	<b>Terms of reference: GAVI Task Force on Research and Development .....</b>	<b>45</b>
<b>Annex 6</b>	<b>Incremental activities related to the management of the Global Fund for Children’s Vaccines Working Capital Account .....</b>	<b>49</b>
<b>Annex 7.1</b>	<b>GAVI Board composition .....</b>	<b>61</b>
<b>Annex 7.2a</b>	<b>GAVI Guiding Principles .....</b>	<b>63</b>
<b>Annex 7.2b</b>	<b>African perspectives on GAVI .....</b>	<b>71</b>
<b>Annex 7.3</b>	<b>Overview of the operations function in the GAVI Secretariat .....</b>	<b>75</b>
<b>Annex 8</b>	<b>GAVI Partners’ Meeting – Noordwijk, the Netherlands November 2000 Provisional programme .....</b>	<b>79</b>
<b>Annex 9:</b>	<b>List of participants .....</b>	<b>81</b>



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# Annex 1.1

## Symposium on poverty alleviation, health and vaccines

### Oslo, 13 June 2000

*Annotated agenda*

**1. Opening speech**

*Prime Minister Jens Stoltenberg*

**2. GAVI – A brief update. Main issues**

*Dr Gro Harlem Brundtland, Chairman of the GAVI Board*

The main purpose would be to give an overview of the main issues and challenges as they have presented themselves during the formation of GAVI. These would include the modalities of participation and representation by partner governments, and the challenges and opportunities associated with GAVI's innovative structure such as its emphasis on broad private public partnership.

An *outcome* of this session would be to arrive at a shared view of how would-be partner governments can work with GAVI and encourage broader participation from civil society, research institutions and private industry in their respective countries.

**3. Poverty reduction – How can GAVI add value?**

*Maj-Inger Klingvall, Minister for Development Cooperation,  
Migration and Asylum Policy, Sweden*

The main objective would be to discuss how GAVI can add value to – become part and parcel of – national poverty reduction strategies in general and the health sector components of such strategies in particular. How can immunization as one of the most cost-effective interventions available for the reduction of morbidity and mortality, with a particular potential for improving the situation of poor and vulnerable groups, best be parried with accessible and sustainable health delivery systems? How can immunization coverage be used as an indicator or “tracer” in measuring progress in health sector reform and poverty reduction strategies? How can research and development of new vaccines against HIV/AIDS, malaria and tuberculosis most effectively benefit the poor?

An outcome of this session would be to arrive at a shared view of GAVI's comparative advantages in terms of supporting the overriding development goal of poverty reduction and national poverty reductions strategies.

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#### **4. Securing additional financing for immunization and vaccine research**

*Timothy Geithner, Undersecretary of the Treasury, USA*

A major purpose of this session would be to discuss how an unusually broad alliance like GAVI can generate additional and innovative resource mobilization for immunization and vaccine research, not only among donors, but also within the developing countries themselves. Is there a need for stronger focus on immunization in health sector programmes financed by development banks and bilateral donors? What is an optimal division of labour between multilateral institutions and governments on the one hand and the market, industry, and civil society on the other? What are the pros and cons of tax credit schemes and similar incentives to stimulate or leverage market solutions. How can we achieve preferential pricing (prices that donor countries and poor people can afford) in the context of a global market?

An outcome of this session would be shared commitment and fresh ideas on how to tap into new or underutilized sources of financing immunization programmes and poverty-related vaccine research.

#### **5. Securing country ownership**

*Dr Lyonpo Sangay Ngedup, Chairman for Council of Ministers and Minister of Health and Education, Bhutan*

This session will take as its premise the recognition that even the most promising development initiative will fail unless the countries concerned claim ownership and provide leadership. How can we ensure that GAVI's programmes become integral parts of national development and health sector plans. What are GAVI's comparative advantages. What are the critical elements that need to be in place for the countries themselves to firmly lead the process of increasing and maintaining immunization coverage? What is the necessary critical mass on the capacity side and how can we best support the required capacity building at country level?

An expected *outcome* of this session would be renewed emphasis on a country ownership perspective in the GAVI process and a reaffirmed commitment to focus on capacity building in order to assist countries and regions to plan for sustainable immunization services with a realistic health system perspective.

#### **6. Partnership and coordination at country level**

*Ms Eveline Herfkens, Minister of Development Cooperation, the Netherlands*

The major aim of this session would be to identify the elements that need to be in place to have a well functioning country-driven coordination mechanism. What coordination mechanisms will serve not only the needs of the immunization efforts, but also link up with broader coordination/partnership arrangements country level, e.g. coordination mechanisms set up to spear-head health sector reform, CGs, UNDAF, CDF, PRSP etc. How can GAVI play a facilitating role in such processes?

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An expected *outcome* of this session would be a shared commitment to strengthen immunization coordination at country level *and* to search for optimal links to coordination mechanisms serving the broader aims of development and poverty reduction.

**7. Summing up of symposium**

*Symposium chair*

The chair will propose that a summary of the discussion be distributed as soon as possible after the symposium and indicate important issues and challenges as well as suggestions for follow-up that such a summary should comprise.



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# Annex 1.2

## Symposium on poverty alleviation, health and vaccines

### Oslo, 13 June 2000

*Summary of the Chair*

*Ms Anne Kristin Sydnes, Minister of International Development, Norway*

#### **1. General observations**

Good health is a stepping stone to democracy. Public sector values, equity and fair distribution are vital to good health. There is a need to restore trust in the public sector, and partnerships that maximize synergies and trust between a range of different actors. There is no need for more of the same, but overcoming some of the barriers of the past and more rapid response.

#### **2. GAVI should be regarded as an instrument for poverty reduction**

Immunization contributes to poverty reduction. National immunization strategies need to aim at reaching out to cover poor and disadvantaged segments of the population.

Immunization coverage data should be used to ensure equitable access to health services, and can also be a powerful tool for measuring progress in equity more broadly. There is a need for advocacy and active use of this indicator in PRSP and CG meetings.

A powerful potential of GAVI for poverty reduction rests with development of new vaccines against HIV/AIDS, malaria and tuberculosis.

#### **3. It is possible to ensure sustainable immunization. GAVI can play an important role**

Immunization services can only be sustained over time if efforts are made to improve the capacity and quality of the health sector in general. This synergy between immunization and the health system must be a prime concern of GAVI. There is a need to rethink how to do development in this respect, and also how to redirect spending to where it matters most and has best returns.

Resources through GAVI and the Global Fund for Children's Vaccines (the Fund) are complimentary to other resources.

An important challenge is to preserve the incentive for innovation, and at the same time deal with questions of cost and affordability. There is a need to expand the overall resource envelope.

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There is also a need to look outside traditional funding mechanisms to do so, such as through tax incentives and new partnerships.

**4. GAVI can only succeed if the processes at country level are country driven and country owned**

Political will is the first important issue, and it must be demonstrated through domestic resource allocations.

GAVI partners must use any opportunity to nurture and stimulate country ownership. Where leadership due to capacity constraints is not sufficiently strong, country-level partners must engage in policy dialogue and design the support in a way that facilitates credible national leadership. GAVI should not substitute for governments' core responsibility.

Strengthening of institutional capacity at country level, ensuring national ownership and country driven coordination are all vital elements in order to achieve sustainable immunization. Community participation and engaging health workers in ownership is critical. Immunization has to be more demand driven.

**5. Coordination and partnership at country level requires commitment from all actors involved**

Coordination must be initiated, organized and driven by countries. Partnerships are required at all levels; global, regional, national and local. On the other hand, new parallel structures must be avoided. Immunization partnerships must establish close links with other coordination mechanisms at country level, including CDF, PRSP and health sector programmes.

A prerequisite for credible partnership with governments is good governance, and willingness to invest own resources.

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# Annex 1.3

## Speech of Prime Minister Jens Stoltenberg to the symposium

Ministers,  
Director-General,  
Excellencies,  
Ladies and Gentlemen,

In 15 years the international community will take stock and ask:

Did we manage by 2015 to half the number of people living in extreme poverty as we pledged during the major UN conferences of the 1990s?

We who are gathered here today have the chance to make it a little bit more likely that the answer will be yes.

The Global Alliance for Vaccines and Immunization is one big joint venture for development.

The United Nations, the World Bank, the private sector and governments from developed and developing countries rally for the cause of health in development.

The ambition is to immunize every child and give them the opportunity to avoid disease and develop their potential.

It is a tall order.

A bold ambition.

A noble task.

I take great pleasure in welcoming the GAVI Board and a number of distinguished ministers and other guests to Oslo.

A special welcome goes to the Director-General of the World Health Organization – or let me be more direct; to Gro.

We have not seen you much in Norway during the last two years.

Welcoming you here today explains why. You are as always busy delivering on your life long promise; to do whatever you can to make a difference. A difference for people's opportunity to take full advantage of their potential and live lives in dignity.

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And nowhere is this noble mission be more needed than in the area of global health.

It is an honour for my government to lend its full support to GAVI's work and objectives.

In developed countries, like Norway, we take so many fundamental rights for granted.

One such right is that every newborn child is offered immunization against killing childhood diseases.

Sometimes we forget that it did not use to be like this.

Not too many decades ago Norway had its share of disease and premature death, especially among children. The gradual building of a national health system went hand in hand with the social and economic development of modern Norway.

And at the core of what the primary health system could deliver was immunization.

Child survival was the key to reduced fertility and more stable families.

Today, we take all of this for granted – as we should in a modern welfare state.

But at the same time it might serve as a wake up call.

Because access or not to routine immunization is one of the many striking illustrations of the differences between the haves and the have-nots in our world.

Because we are getting an impressive amount of knowledge on how much health matters for development of any nation and any people – and above all – how much health matters in the fight against poverty.

Because we learn about new and promising breakthroughs in the area of vaccine research and because there is such an urgent need to make progress in the search for a vaccine against AIDS, malaria and tuberculosis.

And because this is not yet another story of hopelessness.

This is a story of hope, although the challenge is so big.

30 million children grow up without vaccination. About 3 million of them will die as a result.

3 million children. That amounts to 6 every minute – every day, every week, every year.

And yet it is a story of hope.

Because we can do something about it.

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And that is what my government has decided:

We will help immunize every child.

Supporting GAVI is a continuation of Norwegian development policy. We have always focused on health as an important component of our development cooperation.

But at the same time there is something new.

With immunization there is a direct link between what we support and what we achieve.

Much development work is – and has to be – long term. But we also need examples of how development cooperation really matters. Immunizing every child is indeed one such example.

I announced the intention of my Government to actively support GAVI in my inaugural address to Parliament in March. I pledged to offer Norway's support to this initiative, financially as well as politically.

Today I wish to look ahead and make a five year pledge of 1 billion kroner – or about 125 million dollars to the objectives fixed by GAVI. As a first step we will propose to Parliament that Norway grants 200 million kroner for the next budget year. That equals 25 million dollars.

Our support will go beyond filling up a fund.

Let me explain how.

The injection of a vaccine is a powerful illustration of hope.

But all in this room know what it takes to get to the point where a trained health worker can provide that injection.

It takes money.

It takes infrastructure.

It takes trained people.

In short – it takes a health system.

Our support to the GAVI objectives will be an important part of our strategy to support stronger health systems in poor countries.

Health is development, but good health is also a stepping stone to democracy.

In two weeks I will receive President Obasanjo of Nigeria here in Oslo.

Nigeria is key to the future of Africa.

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In 1990 almost 90% of Nigerian children were immunized.

Ten years later that number had declined to 20%.

8 out of 10 Nigerian baby boys and girls enter childhood without the protection of routine immunization.

The toll on Nigeria's future will be high. Because Nigeria's future – as any country's future – depends on its people – their health and their knowledge.

What had happened between 1990 and 1999?

The health system broke down. The infrastructure connecting 36 states in the federal republic disintegrated.

I have been told that enough vaccines were available. But they never reached the ones who so badly needed them.

Because the generals did not care.

Now President Obasanjo – elected by the aspiration of a great people – is rebuilding that infrastructure. From the local level to the federal level. He shares our objective; to help immunize every child.

Those in charge are taking charge. Because in a democracy those in charge are accountable.

Norway will support the people of Nigeria in rebuilding the health system and thereby securing the foundation of democracy.

Rebuilding the infrastructure for immunization can lead the way in rebuilding the primary health care system. To restore trust in the public sector. And thus to restore trust in democracy.

I believe that a strong and competent public sector is key to securing the welfare of Norwegians. And equal access to fundamental welfare services – such as health and care – is a prime result of what a modern democratic government should deliver.

I believe that goes for any country. It goes for Nigeria as well as for Norway.

Last week I spent a day together with President Thabo Mbeki of South Africa and my colleagues from the Nordic countries. On our agenda was how the international community can mobilize new support to Africa.

In the last century Africa won independence. But it lost development.

We agreed to join forces – and actively call on the support by other states and partners to turn the tide in this century. A real agenda for development. And President Mbeki was very clear; at the core of that agenda must be health.

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What should unite us – welfare states and developing countries – is the need for public sector values in the age of globalization.

There are certain things that the market cannot deliver.

Key among them is the value of equity.

It takes a public sector to secure equity and fair distribution of health and education.

GAVI is a vote for the best of such modern global public sector values.

Reaching the poorest.

Long term objectives.

Working in partnership.

Ladies and gentlemen,

Norway will actively support your work.

Immunizing every child is a noble task.

When I took office I was asked what I wanted my government to be remembered for.

I took some time to reflect. Because ours is an agenda of many ambitious goals.

Then I thought: It would be an honour if we were be remembered for having made a real impact in helping immunize every child in the world.

Because nothing offers more hope than a healthy child ready for life.



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# Annex 2.1

## Country proposal review process – basic principles

*Presented by Michel Zaffran, WHO*

1. The country proposals for support to the Global Fund for Children's Vaccines (the Fund) must be received at the GAVI Secretariat by specific dates set annually, about which the eligible countries will be notified.
2. The proposals will be screened by the Secretariat for completeness and basic eligibility.
3. The proposals will then be submitted to an independent committee of experts whose members will be selected by the Executive Secretary after consultation with the Working Group. The paramount consideration in this selection shall be a broad expertise in health with specific knowledge of vaccines and immunization, independence from the partners of GAVI, and integrity. Due regard shall be paid to the importance of selecting experts on as wide a geographic basis as possible. Primarily these experts should be selected from low- and middle-income countries.
4. A confidentiality and conflict of interest statement to be signed by review committee members is attached.
5. The committee will review these proposals in accordance with the policies laid down by the Board and following the criteria for eligibility and assessment as expressed in the guidelines prepared by the Working Group.
6. In light of the results of this review, the committee will formulate recommendations which will be communicated to the Board for final decision.
7. The following time-table has been developed for the conduct of the first round of reviews of country proposals:
  - a) Country proposals must be received at the Secretariat by 1 July 2000.
  - b) The review committee will convene in Geneva from 8 to 12 July and will formulate its recommendations. Its composition is attached. (On an exceptional basis and to gain experience, it is contemplated that the Working Group meets with the review committee on an informal basis on 12 July to exchange views on the committee's recommendations, and that the Working Group and the available members of the Board further deliberate the committee's recommendation on 13–14 July.)
  - c) The recommendations will be forwarded electronically to the Board for its final decision.

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## Confidentiality and conflict of interest statement

1. The Global Alliance for Vaccines and Immunization (GAVI) has access to certain Information relating to vaccines or related products which it considers to be proprietary to itself or to parties collaborating with it (hereinafter referred to as “the Information”).
2. The Undersigned, as a member of the independent committee of experts (hereinafter referred to as “the committee”), may have access to the Information in the course of his/her participation in the committee.
3. GAVI is willing to provide to the Undersigned the Information for the purpose of performing his/her responsibilities in connection with the activities of the committee provided that the Undersigned undertakes to treat the Information as confidential and to disclose it only to persons who are bound by like obligations of confidentiality and non-use as are contained in this undertaking.
4. For the duration of the membership of the Undersigned in the committee and for a period of five years following the termination of membership, the Undersigned undertakes to regard the Information as confidential and proprietary to GAVI and agrees to take all reasonable measures to ensure that the Information is not used, disclosed or copied, in whole or in part, other than as provided in this undertaking except that the Undersigned shall not be bound by any such obligations if he/she is clearly able to demonstrate that the Information:
  - a) was known to him/her prior to any disclosure by GAVI to the Undersigned; or
  - b) was in the public domain at the time of disclosure by GAVI or
  - c) becomes part of the public domain through no fault of the Undersigned; or
  - d) becomes available to the Undersigned from a third party not in breach of any legal obligations of confidentiality to GAVI.
5. The Undersigned also undertakes not to communicate the deliberations and decisions of the committee to persons outside this committee except as agreed by the committee itself or by GAVI.
6. The Undersigned agrees not to participate in the review of any matter under consideration by the committee if such a participation may give rise to a real or perceived conflict of interest. The Undersigned agrees to promptly disclose any such possible conflict of interest to GAVI. Conflict of interest means that the Undersigned, his/her spouse, child or collaborating investigator, or an entity with which the Undersigned has an employment relationship or collaborative arrangement, has an existing or potential financial or other interest that either could unduly influence the Undersigned’s position with respect to the subject-matter of the work of the committee or could result in the Undersigned’s objectivity and independence being questioned by others.
7. Any dispute relating to the interpretation or application of this undertaking shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

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## Independent Review Committee, First Round – July 2000

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# Annex 2.2

## Estimated timing of submission of country proposals to GAVI

*(updated July 2000)*

<b>The following countries submitted proposals to GAVI for the first round of review in July 2000</b>		
1. Bhutan	9. Haiti	17. Mozambique
2. Cambodia	10. Kenya	18. Pakistan
3. Central African Republic	11. Kyrgyz Republic	19. Rwanda
4. Chad	12. Lao PDR	20. Sierra Leone
5. Côte d'Ivoire	13. Liberia	21. Sudan
6. Ghana	14. Madagascar	22. Tanzania, United Republic of
7. Guinee	15. Malawi	23. Yemen
8. Guyana	16. Mali	24. Zimbabwe

<b>The following have indicated their intention of submitting country proposals by October 2000</b>		
1. Albania	9. Guinea Bissau	17. Tadjikistan
2. Armenia	10. Honduras	18. Turkmenistan
3. Bangladesh	11. Lesotho	19. Uganda
4. Burkina Faso	12. Myanmar	20. Uzbekistan
5. Cameroon	13. Nepal	21. Viet Nam
6. Cuba	14. Nigeria	22. Zambia
7. Eritrea	15. Senegal	
8. Georgia	16. Sri Lanka	

<b>The following have indicated their intention of submitting proposals by April 2001</b>		
1. Burundi	2. Comoros	

<b>Countries with large populations and their own vaccine production capacity will require specific negotiations:</b>		
1. China	2. India	3. Indonesia

<b>The following countries have not indicated when they will submit their proposals:</b>		
1. Afghanistan	9. DR Congo	17. Niger
2. Angola	10. Ethiopia	18. Papua New Guinea
3. Azerbaijan	11. Gambia	19. Sao Tomé & Principe
4. Benin	12. Korea DPR	20. Solomon Islands
5. Bolivia	13. Mauritania	21. Somalia
6. Bosnia and Herzegovnia	14. Republic of Moldova	22. Togo
7. Congo	15. Mongolia	23. Ukraine
8. Djibouti	16. Nicaragua	

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# Annex 3:

## GAVI and the Polio Eradication Initiative (PEI)

*Presented by Yves Bergevin, CIDA*

On 10 May 2000, members of the GAVI Working Group attended the Fifth Meeting of the Global Technical Consultative Group for Poliomyelitis Eradication to discuss areas for collaboration. The following is an outline of the Working Group's presentation to the meeting, and an extracted summary from the draft meeting report.

### **Working Group Presentation**

#### ***GAVI Policy Direction***

- Understanding that polio eradication is a time limited initiative while GAVI has broader and long-term goals.
- GAVI seeks to maximize complementarity between PEI and GAVI missions through close collaboration.
- Collaboration will be considered on a country-by-country basis, strongly respecting the final needs of the polio eradication effort, and the broader mission of GAVI.

#### ***GAVI and PEI could work together to explore a more complementary partnership***

- How can PEI and GAVI each benefit from their respective strengths, recognizing that:
  - PEI has extensive human resources in the field but is under acute time requirements;
  - GAVI has a long-term need for human resources;
  - both PEI and GAVI require additional funds to meet their objectives.

#### ***GAVI will collaborate with PEI by:***

- Working with all countries to improve their routine delivery of vaccines including OPV.
- Providing additional resources to the poorest countries' immunization programmes that require significant improvement in service delivery.
- Strengthening all national/regional ICCs to monitor all aspects of immunization programmes.

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- Ensuring that the appropriate strategies for polio eradication are included in the national multi-year plans for immunization developed for application to the Global Fund.
  - In endemic countries, reinforcing polio as a priority.
  - Targeting the support for new vaccines to countries with more robust immunization programmes (>50% coverage) and, in those countries, carefully integrating the vaccine into the routine system to minimize the burden (focus on combinations).
  - Suggesting that AFP surveillance be included as an indicator for monitoring immunization programme quality.

### **Summarized from the draft report of the TCG meeting**

The recent formation of the Global Alliance for Vaccines and Immunization (GAVI) presents a good opportunity to strengthen immunization programmes and enhance efforts to eradicate poliomyelitis from the world.

However, a number of major polio partners have expressed concern that this opportunity has not yet translated into direct support for country level implementation of polio eradication strategies. Furthermore, there are reports, particularly from the regional and intercountry level, that demands on polio-funded immunization staff to assist in GAVI-related activities, such as the preparation of applications for funds from the Global Fund for Children's Vaccines, would be substantially increased. If confirmed, their time available to work on polio eradication would be substantially decreased.

Several actions were recommended by the TCG that would enhance the interaction of the polio eradication initiative with other GAVI activities. They include:

- Inclusion of the certification of the eradication of poliomyelitis by 2005 as one of GAVI's milestones, and conversely, inclusion of the GAVI milestone for improved routine immunization (80% coverage in 80% of districts) in the Polio Eradication Strategic Plan.
- Enhancing communications between the Polio Eradication Initiative and the GAVI Working Group.
- Encouraging countries that are critical to the success of polio eradication to apply to the Fund for support in strengthening immunization infrastructure, particularly with respect to the cold chain, transportation, and communications.
- Encouraging countries to use AFP surveillance as one of the GAVI performance criteria in monitoring national programme quality.
- Securing funding from GAVI partners for additional staff at regional and country levels to assure effective implementation of GAVI activities while promoting polio eradication.

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# Annex 4.1a

## UNICEF commitment to vaccine supply and the vaccine industry

*Presented by Steve Jarrett, UNICEF Supply Division*

### **Basic principles**

- UNICEF recognizes Immunization as an important and cost effective intervention that can enhance the right of all children to a healthy life, and that has positive effects in combating poverty.
- UNICEF recognizes the vital role of the Vaccine Industry in world health improvement and the need for a thriving Industry globally which supports immunization activities and actively engages in the continuous search for new vaccines of high quality, including those of relevance to children in developing countries.
- UNICEF, in recognizing the critical contribution of vaccines to the achievement of public health gains, acknowledges that the low relative commercial value of vaccines within the global pharmaceutical market creates significant challenges for ensuring sufficient capacity for the production of existing vaccines and for maintaining long-term investment in research and development of new vaccines.
- UNICEF recognizes that the Vaccine Industry is instrumental in generating solutions to ensuring the affordability of vaccines, at 'significantly discounted' prices for the poorest countries, and to improving delivery technologies for developing countries.<sup>1</sup>
- UNICEF commits itself to establishing and maintaining a Constructive Partnership with the Vaccine Industry in the effective supply of existing vaccines and in accelerating the introduction of underused and new vaccines, through effective and continuous dialogue at all levels.
- As a principal purchaser for immunization programmes in developing countries, UNICEF commits itself to enhancing reliability and predictability in vaccine demand and supply, strengthening the planning and forecasting of vaccine needs in the immunization programmes it supports and ensuring that updated information is readily available to Industry.
- UNICEF recognizes the shortcomings in short-term tendering for vaccines focused principally on prices and commits itself to longer-term purchasing arrangements, wherever appropriate, that can provide incentives to Industry, including wherever possible guaranteed minimum volumes of vaccines to be purchased, to ensure the sustained supply of vaccines over longer periods.

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<sup>1</sup> Commitment of Industry at World Economic Forum, Davos, 31 January 2000.

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- UNICEF acknowledges the principal of competition in the supply of vaccines and will actively engage all qualified suppliers with an established track record of production that submit acceptable bids or proposals for the supply of vaccines of appropriate quality to UNICEF. UNICEF makes multiple awards for any single product, each award equating to a percentage share of the market covered by UNICEF purchases. Timeliness and continuity of supply are important to UNICEF and UNICEF calls on Industry to hold emergency or buffer stocks of vaccines, wherever appropriate, for immediate availability.
  - UNICEF commits itself to advising Industry openly the criteria it uses to make awards for establishing specific purchase arrangements and agreements, and opens all bids and proposals publicly with the invited participation of Industry.
  - UNICEF recognizes the importance of innovation in the vaccine sector and commits itself to working with Industry to ensure the accelerated introduction and delivery of underused vaccines to benefit children most in need, recognizing that success in the delivery of underused vaccines will greatly motivate increased research and development of new vaccines, including those of relevance to children in developing countries.
  - The long-term vision of UNICEF is to move to supplying affordable combination vaccines in pre-filled single dose devices, with needles or preferably needle-less, as the safest and most effective delivery possible of vaccines.

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## Procurement Action

- UNICEF invites WHO-qualified manufacturers to bid for 5-year purchase arrangements (2001–2005) for OPV and 3-year purchase arrangements (2001–2003) for other ‘mature’ vaccines (measles, MMR, DPT, DT, TT and BCG) for delivery among all developing countries that use UNICEF procurement.
- UNICEF, as procurer for vaccines financed by the Global Fund for Children’s Vaccines, invites WHO-qualified manufacturers to provide proposals for 3-year agreements (2001–2003) for immunizing specific numbers of children with ‘underused’ products (HepB, Hib, yellow fever). Proposals can incorporate the stated intent of Industry to contribute actively to GAVI objectives for the accelerated use of these vaccines in developing countries, especially the poorest.
- For ‘underused’ products, UNICEF purchases for the poorest countries in the world as a Poorest Countries Market<sup>2</sup> and purchases vaccines for other countries, if requested, as Country-Specific Markets. UNICEF encourages Industry to offer ‘significantly discounted’ prices to the Poorest Countries Market and commits itself to not considering these as reference prices for Country-Specific Markets. UNICEF commits to engaging itself to ensure that the vaccines it buys or receives as contributions (donations) for the Poorest Countries Market are not diverted to other markets.
- UNICEF is pleased to accept contributions-in-kind of vaccines meeting WHO criteria, and determines the value according to its current prices for the product. In the case of contributions-in-kind that are linked to purchases, these are considered together with the purchase at a discounted price.

***UNICEF has active policies of not working with companies using child labour or producing land mines or parts thereof. Any commercial arrangements for the supply of life-saving products, including vaccines, entered into with companies considered to be conducting practices in violation of the Code on the Marketing of Breast-milk Substitutes in no way implies an acceptance of these practices.***

***UNICEF Supply Division Proposal, 31.5.2000***

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<sup>2</sup> Countries with GNP/capita under \$1000, according to latest published World Bank statistics, and population under 150 million, according to latest published UN statistics – currently 71 countries.



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# Annex 4.1b

## GAVI vaccine donation policy

A number of vaccine producers have indicated an interest in donating vaccines to GAVI. Following are proposed guidelines specific to a GAVI donation policy:

- To the maximum extent possible, vaccine donations will be considered as in-kind contributions to the Global Fund for Children's Vaccines.
- Donated vaccines would be directed to countries that have been approved through the GAVI review process for country support from the Fund.
- The active participation of the vaccine producer in the shipment, distribution, training and capacity-building relating to the safe use of vaccines is strongly encouraged.
- GAVI partners will need to consider whether the Fund should accept all types of vaccines or only newer vaccines and vaccine combinations that contain newer vaccines (such as DTP-hepB-Hib).

Basic UNICEF/WHO vaccine donation guidelines are provided below.

### **UNICEF/WHO vaccine donations guidelines**

A vaccine donation is defined as a shipment of vaccine for which a government does not pay. Properly managed, vaccine donations are useful to immunization programmes. However, if there is no control over the specifications of the vaccine, or if the donated vaccine does not meet the needs of the government's immunization programme, the donation could leave a country vulnerable to problems and actually disrupt the programme. Furthermore, a vaccine donation must be part of a sustainable vaccine supply; if, once the donated supply is exhausted, there is no provision for sourcing the vaccine, the sustainability of the immunization programme is threatened.

The aim of these guidelines is to improve the management of donated vaccines, and not to hinder donations. Vaccines shipped through UNICEF Supply in Copenhagen may technically be considered as donations, but as their specifications are developed by a collaborative effort between national officials and UNICEF country staff, such vaccines are not included in these guidelines.

Most recipients of vaccine donations are countries dependent on UNICEF and other donors for their supply of vaccines. Many lack infrastructure to handle donations adequately. WHO recommends that all countries, including those which receive all their vaccines from UNICEF, exercise at least two essential national control functions:

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a published set of requirements for licensing or other control procedures appropriate to the country's needs, and surveillance of vaccine field performance (monitoring of adverse events following immunization). In the case of a problem in the field which may be vaccine related, or of doubt of vaccine potency because of a cold chain break in transport, UNICEF can be notified and, if vaccine testing is needed, WHO laboratories can be used.

WHO has already published guidelines for receipt of donations of drugs (WHO/DAP/96.2). For the most part, these guidelines are applicable for vaccines as well. Five proposed minimum specifications for vaccine donations restate these guidelines in a manner applicable to vaccines:

- The vaccine is epidemiologically appropriate for the immunization programme; that is, the donated vaccines are consistent with the goals of the immunization programme.
- The vaccine is subject to prescribed licensing and or other control procedures set up by the recipient government, and is in compliance with quality standards in both donor and recipient countries.
- The vaccine is consistent in presentation and specifications with other vaccines in the programme; that is, the donated vaccine should be familiar to the health professionals in the recipient country in such characteristics as potency, liquid or freeze-dried presentation, transport, shelf life, number of doses per vial, thermostability, and label language and information.
- Responsible officials in the recipient country should be informed of all donations that are being considered, prepared, or actually under way, and the vaccine should be shipped only on their request.
- Prior to the donation of a vaccine that is new to the recipient country, efforts should be undertaken to assure sustainable use of the vaccine after the period of donation.

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# Annex 4.2

## Financial sustainability in year six and beyond

*Presented by Chris Lovelace, World Bank*

Immunization is an integral part of health service delivery. Countries need to have access to high quality, safe, available, and affordable vaccines. While international assistance has a critical role to play in the short to medium term, the aim should be long-term sustainability and self-financing.

### **Global Fund for Children's Vaccines**

As currently conceived, the Global Fund for Children's Vaccines (the Fund) will provide support to countries to improve their infrastructure for delivering vaccines. The Fund can also provide some or all of the hepatitis b, yellow fever, and Hib vaccines for an initial term of five years. But what happens in year six?

In providing funding alone without addressing longer-term financing, there is a danger that countries will become totally dependent on external funding, unable or unwilling to finance the full programme costs when Fund funding ends.

If the Fund is re-capitalized, post-2005 funds are expected to support the next generation of "new" vaccines such as a pneumococcal vaccine, or potentially the next generation rotavirus vaccine. As part of the current Fund requirement, each country must develop plans outlining how immunization activities will be financed at the end of year five. These plans will be reviewed at the end of the second year of funding.

The best case scenario is that over the initial five-year period of the Fund, countries will plan and budget to finance the new vaccines and infrastructure investments needed to maintain high immunization coverage rates into the future.

The worst case scenario is that over this same period, countries will not develop plans to finance new vaccines and infrastructure investments; donor fatigue will set in as new initiatives attract attention and resources; and newly introduced vaccines will be discontinued and programmes fall apart in year six.

What actions can the GAVI partners take now to increase chances of the best case scenario being met?

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## Background Information

### *Costs of National Immunization Programmes*

The full cost of national immunization programmes represents a small percentage of overall public health spending—less than 5% in many countries. Furthermore, recent studies of national immunization programmes indicate that their costs per capita are low – less than US\$ 1.00.<sup>3</sup> Given the cost-effectiveness of routine immunization using the recommended vaccines, it is one of the best uses of government funds. It is thought that, in time, even low-income countries should be able to pay for a substantial portion of their national immunization programmes.

### *Current Financing Mechanisms*

Currently, immunization is financed largely by governments and bilateral donors. Bilateral donors usually operate on a one-year funding cycle and financing commitments tend to be limited to one year. There is some support through loans and credits from the World Bank and regional development Banks.

However, some governments have expressed their reluctance to increase their debt load to cover recurrent expenses (e.g. vaccine procurement) as contrasted with investments in infrastructure and capacity building. In addition, many governments have come to expect grant financing for immunization and are unwilling to accept concessionary funds from the Banks (concessionary funds are roughly 75% grant). The World Bank is currently exploring options to expand the flexibility of International Development Assistance (IDA) funds to make lending more applicable to health initiatives, but this is likely to be a lengthy process.<sup>4</sup>

Other immunization financing mechanisms include two revolving funds (PAHO Revolving Fund and the Vaccine Independence Initiative (VII)) and one grant mechanism ARIVAS (European Union's Appui au renforcement de l'indépendance vaccinale en Afrique sahélienne).

The PAHO Revolving Fund is essentially a procurement mechanism with strong technical assistance and advocacy components. As a procurement instrument, the fund collects the requests of many countries to obtain lower vaccine prices. As a management tool, access to the fund is limited to countries that have long-term programme plans and that pay promptly for vaccines ordered through the fund. The VII has two goals: to assist countries to pay for vaccines themselves (countries pay for vaccines in either hard or local currency depending on the absorptive capacity of the UNICEF country programmes); and to encourage governments to gradually increase their share of financing. ARIVAS is a grant providing budgetary support to countries to pay for vaccines and supplies.

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<sup>3</sup> The costs per capita of National Immunization Programs were \$0.28 in Bangladesh, \$0.40 in Morocco, and \$0.61 in Cote D'Ivoire in 1998 (Abt Associates, Partnerships for Health Reform, 1999)

<sup>4</sup> For more information on IDA loans, please see GAVI Financing Task Force's *Incentives for Accelerated R&D for Priority Vaccines*, prepared for GAVI Board, June 2000).

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It is unclear to what extent these funding mechanisms have actually led to an increase in financial sustainability of immunization programmes. The partners within the Financing Task Force are currently conducting evaluations of the VII, ARIVAS, and PAHO Revolving Fund. These reviews are expected to look more closely at the issues of long-term sustainability. In addition, UNICEF is reviewing plans to restructure the VII to address issues of sustainability.

### Questions to the Board

1. Given that governments are required to submit long-term plans for financing vaccines and immunization costs, are there specific elements or strategies that should be required? For example, these plans could be required to contain the following components:
  - Phasing-out of future Fund contracts.
  - Spread of Fund resources for purchase of vaccines over a longer period of time, for example partial funding for eight years instead of full funding for five years.
  - An immunization line item in the government budget.
  - Signature of endorsement from the Ministry of Finance.
2. Should GAVI partners set and monitor sustainability targets for countries and donors? If so, how should these targets be set?
3. The Bank is working to increase lending for immunization, but countries frequently refuse Bank credits as they prefer grant money. How can governments be encouraged to request Bank support for immunization? Can GAVI partners play a role in this? Should other funding sources be explored to contribute to the overall financial needs of governments?
4. Is there a role for advocacy in increasing national ownership and thereby long-term financial sustainability? If so, should the Advocacy Task Force be charged with this objective? What information would be useful to this campaign?



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# Annex 4.3

## Incentives for accelerated R&D for priority vaccines

*Presented by Amie Batson, World Bank*

The development and use of new vaccines against highly infectious diseases is a public good with tremendous benefits for the world. Unfortunately, market and institutional failures have skewed investments away from vaccines that address the problems that predominate in developing countries. The unwillingness or inability of governments and partners to finance the existing priority vaccines heavily influences industry's perception of the probable future market for new products for the developing world. The resulting under-investment in R&D is hindering the development of needed products against priority diseases such as HIV/AIDS, malaria, and tuberculosis.

Since the establishment of GAVI, two important mechanisms to encourage new vaccine development are being implemented:

1. The use of the Fund to stimulate new markets in low-income countries for currently available yet underused vaccines.
2. A new system for vaccine procurement that includes longer-term purchasing arrangements that can provide incentives to Industry, and enhanced reliability and predictability in vaccine demand and supply.

However, these efforts are not sufficient for the substantial task at hand.

To better understand this market failure, the GAVI Financing Task Force (FTF) has identified a number of actions in its work plan. Many of the activities have been implemented through the World Bank's work with government and industry partners which explores the factors influencing investment decisions and identifies possible public actions to help accelerate the development and introduction of priority health products such as vaccines. Using HIV/AIDS vaccine as a case study, the Bank systematically interviewed biotechnology, vaccine and pharmaceutical firms to understand their perspectives of the market and the economics driving R&D. Further consultation with governments, technical partners and industry helped to define the possible roles of the public sector.

Options to accelerate the development of a vaccine were categorized as **push strategies** which reduce the risks and costs of R&D investment, and **pull strategies** which provide a market incentive for product development. It was noted that the development and scale-up of a vaccine is a dynamic process during which a vaccine moves through different stages. Understanding each stage provides insight into the specific constraints facing a developer at different points in the process.

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The Bank's study found that because development is a composite problem, no single "silver bullet" solution, market based or otherwise, would be adequate. Instead a mix of push and pull strategies was necessary to ensure the product was not only developed but also adequately tested in and/or adapted to developing countries, and scaled-up for global capacity. Push strategies tended to be more important early in the development cycle when the risks or uncertainties of creating a product which would prove effective were highest. Pull strategies became more important once the product had been shown to work in at least one target population but investment was still required to broadly test, adapt and scale-up the product for developing country need.

Given the objective of rapid availability of a new vaccine, the study noted the difference between the pattern of development/investment for the existing range of vaccines and what would be needed for new vaccines. Currently, existing vaccines only reach "affordable" prices once the market matures, creating competition and over-capacity and thus a willingness to sell at marginal prices. There is minimal investment in R&D or capacity to serve developing countries—and to date, the public sector has shown little willingness to finance any level of investment. While the current approach has resulted in very low prices eventually, the penalty has been slow development of new products and 10–15 year waits before existing products reach mature levels and low prices.

A decision that a new vaccine should be made broadly available at the earliest possible technical and regulatory opportunity would require a manufacturer to make development and capital investments explicitly to support supply to the developing world markets. Industry would make these investments if they were confident that a reasonable return would be forthcoming. However, this, in turn requires that the public sector have in place commercially credible funding, pricing and supply policies.

A number of different pull options were identified during the Bank's study. These options include:

1. Expanded lending for existing vaccines : Stimulating the developing country market for existing vaccines would start to "fix" the overall market and provide much greater credibility to long-term promises to guarantee a market for a future vaccine.
2. Providing better information on developing country markets: Private firms' decisions to invest in R&D for vaccines, as with other products, are highly dependent on their perception of some future lucrative market for sale of that product. To date, investment decisions have been based almost exclusively on the potential market in industrial countries. Better information on the characteristics of vaccines that are likely to be demanded in developing countries and on the responsiveness of both public and private purchasers for any new vaccine may alert firms to an important market segment they might otherwise ignore.

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3. **Market assurances:** Yet even with better information, increased knowledge of the potential developing country market for an appropriate new vaccine alone is unlikely to be sufficient to change firms' R&D behaviour because: (a) the potential commercially viable market may be small; and (b) there is still great uncertainty as to whether the potential market will materialize. Uncertainty about the future market for a priority new vaccine in developing countries can be substantially reduced through agreements that "guarantee" purchase of an appropriate vaccine, if it is developed.
- a) **Contingent vaccine purchase fund.** A new trust fund, or a new subaccount of the Fund, could be established for the purchase of a vaccine for the poorest countries or to provide matching funds to enhance developing country budgets. The trust fund could be capitalized by contributions primarily from industrialized countries, although middle-income countries could also be invited to contribute. The trust fund could be financed now, allowing the fund to accrue interest, or financed in the future through government pledges or promissory notes. The trust fund monies would become available only if and when a vaccine was developed that meets very specific criteria, in terms of its price, effectiveness, and applicability for developing countries. This option has significant opportunity costs.
  - b) **High-profile international public signing of intent.** Public visibility can be a powerful incentive for public action and strengthen the commitment of the international community to eventually purchase a priority vaccine for developing countries. GAVI could coordinate public pledges to purchase a vaccine by donors and countries, in international forums with wide press coverage and attendance of heads of state or other high officials. This would give greater prominence to the problem of generating adequate R&D on vaccines that are international public goods.
  - c) **Replenishing source of IDA resources to address communicable diseases:** Using resources from IDA, and possibly also from other multilateral concessional funds, a "replenishing" source of finance could be established to accelerate development of and access to priority new vaccines for the poorest countries. These funds could be "topped off" as necessary through successive IDA replenishments, to provide financial commitment for new drugs and vaccines as they are developed. In the immediate term, resources could be used to support countries to strengthen delivery systems and provide interim financing for the purchase of existing, cost-effective products. In the long-term, governments will must include the costs of their national immunization programme and vaccines into national budgets. In the future, priority use might be for the purchase of new technologies such as AIDS or malaria vaccines or TB drugs, once the price and efficacy of the technologies reaches the point at which they are cost-effective relative to other conventional prevention programmes. The World Bank is working actively to implement this initiative and will be discussing options with the IDA deputies during their June meeting.

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4. **Tax credits:** governments in large industrial countries can provide tax incentives to either stimulate greater investment in R&D or encourage development and sales of priority vaccines in developing countries. The U.S. Government is exploring a US\$ 1 billion tax credit which would be applied against the sales of AIDS, malaria or TB vaccines channelled through agreed upon organizations.
  5. **Transferable patent extension:** Patent extensions in the largest industrial country markets might stimulate greater interest from large pharmaceutical companies in the field, in turn providing a stimulus to candidate and development efforts, especially in the biotech sector. In addition a patent extension has the advantage that, while it is worth several hundred million dollars to any major pharmaceutical company, its costs are hidden. The cost to the industrial country healthcare systems could nonetheless be justified by the future healthcare savings which would be generated by success development of a vaccine. This option would require extensive legal and political groundwork.

There are a number of initiatives designed to explore and/or coordinate partners in pull options including:

- **GAVI Financing Task Force:** The work plan explores pull options for vaccines and seeks to implement at least one through partners, particularly the World Bank and its Communicable Disease Effort.
- **WHO-IFPMA Pharmaceutical Roundtable:** Explores push and pull options for all pharmaceuticals.
- **Commission on Macro-Economic Health, Working Group #2:** Explores pull options for all health products with a focus on vaccines.

### **Questions to the GAVI Board**

1. Pull strategies can only be achieved with the highest level buy-in and active involvement of multiple partners. What information would help the GAVI partners, particularly those represented on the Board, need to first prioritize options and second, to work together to implement specific pull strategies?
2. Each of the aforementioned initiatives contributes greatly to the overall knowledge and work in the area of push-pull mechanisms. Unfortunately, however, a small number of private industry and public sector representatives are being asked to attend numerous meetings with very similar objectives. With specific reference to its vaccine-related work and given the other initiatives under way, how should GAVI proceed with its coordinating role? And more specifically, what pull work should the FTF take-up or leave aside for other coordinating initiatives?

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# Annex 5

## Terms of reference: GAVI Task Force on Research and Development

*Presented by Mike Levine, University of Maryland*

During the past three decades, the critical role of vaccine research and development as an indispensable tool of public health has become increasingly appreciated. Research can be viewed as a continuum that includes four discrete stages, as follows:

1. Measurements of disease burden.
2. Basic laboratory research leading to the generation of candidate vaccines or related products (e.g. technologies that enhance vaccine safety or simplify vaccine delivery).
3. Clinical trials to assess the safety, immunogenicity and efficacy of the vaccine (or related product or technology).
4. Post-licensure studies to demonstrate the impact and effectiveness of the vaccine (or related product or technology) and its long-term safety under routine programmatic conditions.

To begin to address the GAVI objective of accelerating the development of vaccines and related products of particular importance for developing countries, a meeting of a pre-task force on research and development was convened in Geneva on 4–5 November 1999, cosponsored by GAVI and by the Intercluster Vaccine Research Initiative (IVR) of the World Health Organization<sup>5</sup>. The Board is now requested to consider the establishment of a Research and Development Task Force.

### **Mission**

The Task Force on Research and Development will assist in coordinating the GAVI partners to achieve GAVI's objectives 3 & 4 (i.e. "Accelerating the development and introduction of vaccines; and, "Accelerating the research and development efforts for vaccines and related products specifically needed by developing countries, particularly vaccines against HIV/AIDS, malaria and tuberculosis").

There are numerous institutions involved in research and development of vaccines and related products and technologies. The Task Force will therefore take a strategic approach to strengthen exciting avenues of research rather than developing new ones.

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<sup>5</sup> A report of this meeting has been circulated earlier to GAVI partners and is attached as background information.

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## **Broad objective**

### ***Enhance communication, collaboration and inclusiveness.***

The global vaccine research community includes many diverse players, each contributing in different ways with vastly heterogeneous resources and distinct agendas. Much can be gained by coordinating agendas and goals to render efforts complementary, avoid duplication and maximize the use of limited resources.

There is a need to enhance the exchange of technical and strategic information among the various GAVI partners involved in research (particularly where the research impacts on health problems of developing countries).

The many partners involved in vaccine research and development activities and epidemiologic studies in both industrialized and developing countries must be represented in a truly synergistic effort. Partners include governmental research institutes, academic research programmes, large vaccine manufacturers, biotechnology companies, units within ministries of health, etc. There are also partners that are not primarily engaged in research but who, as implementers of immunization, will provide critical input to researchers to advise them on what is needed, feasible, and desired at the front lines of primary care, and in contrast, what cannot be readily incorporated into primary care regimens.

### **Some specific objectives**

The Task Force will help coordinate, facilitate and monitor the progress of research and development of:

- Developing market vaccines against diseases for which the burden is largely limited to the developing countries.
- Vaccines that may be useful in preventing infectious diseases that are important in both developing country and industrialized country populations.
- Innovative generic technologies intended to enhance vaccine safety and/or to simplify immunization.
- Simple, practical laboratory assays (such as serologic tests to monitor the outcome of vaccination or antigen detection kits to diagnose specific infections) that can facilitate the measurement of disease burden and assessments of vaccine effectiveness.
- Rapid field assessment methods to estimate disease burden and vaccine effectiveness.
- Productive, mutually beneficial relationships among public sector research programmes, and industrialized and developing country manufacturers of vaccines and related products, to build capacity within countries and transfer relevant technology to developing country industry. It will also enhance the global community's ability to sustain a long-term supply of the desired new vaccines, serologic tests and diagnostic kits.

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## Major activities

1. To convene annually, in conjunction with the IVR of WHO, an annual Global Vaccine Research Forum to include representatives of the various partners involved in research or who need to have input into guiding research. The goal of this meeting will be to enhance communication and coordination among the research agendas of the various partners, without compromising the independence of any partner.
2. To discuss and set broad global research and development priorities that allows each partner to contribute in the way they deem most appropriate towards achieving the consensus goals.
3. To promote partner groups to accelerate development of priority vaccines. These groups will outline the activities needed to accelerate each step in the research continuum including disease burden studies, basic laboratory work, pre-clinical trials and post-licensure studies, identifying which partners are undertaking each activity.
4. It is anticipated that these groups will address distinct areas, for example: a) disease-specific (e.g. AIDS, malaria, tuberculosis, diarrhoeal diseases, leishmaniasis, sexually transmitted diseases), b) new generic vaccination technologies (e.g. thermostabilized vaccines, adjuvants, mucosal and transcutaneous immunization), c) vaccine delivery technology, d) capacity building and technology transfer. The subgroups would be led by one partner and use to the maximum extent possible existing groups.
5. To identify “roadblocks” or shared objectives cutting across multiple vaccine work plans and identify steps to address them. These “push” topics may include, for example, establishing partnerships with industry, patent protection, facilitating access to pilot lot formulations, financial and technical support for clinical trials, and ways to make clinical trials simpler and more economical.
6. To work with the Task Force on Financing which is coordinating the efforts of partners to create “pull” mechanisms that will serve as incentives to increase investment in R&D.
7. Once global priorities have been discussed and set, the Task Force will periodically review the work plans and the status of relevant research and development to identify gaps and obstacles.

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## **Composition**

- The Working Group recommends that the Task Force should be co-chaired by Academia, Industry and WHO.
- In order to be effective, the Task Force should ideally not have more than 8–10 members, in addition to the three co-chairs.
- In order to facilitate the broad objectives, the Working Group recommends that the Task Force draw upon individuals from existing Advisory Boards of implementing partners such as national medical research councils, academic institutions, industry and existing scientific review and advisory committees of WHO (e.g. SAGE & STAC), Gates Children’s Vaccine Program, International AIDS Vaccine Initiative, International Vaccine Institute, Malaria Vaccine Initiative, etc.
- The Task Force will have a full-time secretary, if required, sponsored either through the GAVI secretariat or through the generosity of one or more GAVI partners.

## **Reporting**

- The Task Force will initially bring the needs in Research and Development to the attention of the GAVI board. The Board will then assess how partners can meet the needs.

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# Annex 6

## Incremental activities related to the management of the Global Fund for Children's Vaccines Working Capital Account

*Presented by David Alnwick, UNICEF*

### Contents

<i>Executive summary</i> .....	50
1. UNICEF – the United Nations Children’s Fund .....	51
2. UNICEF commitment to GAVI and immunization .....	52
3. Management of the Fund Working Capital Account at UNICEF .....	53
5. Reporting .....	60
The Mission of UNICEF .....	60

## Executive summary

The Global Alliance for Vaccines and Immunization (GAVI) was launched in January 2000 with the mission of ensuring that every child in the world is protected against vaccine-preventable diseases. With an initial contribution of US\$ 750 million from the Bill and Melinda Gates Foundation, a Global Fund for Children's Vaccines (the Fund) has been established and will be used to strengthen immunization systems in the poorest countries, procure vaccines and accelerate research and development of new vaccines against diseases such as malaria, tuberculosis and HIV/AIDS.

Within the framework of GAVI, UNICEF will participate as a main partner in the shaping of the global agenda on immunization. UNICEF will be represented on the GAVI Board – and hold the chair in the second term – on the global Working Group, in the various GAVI Task Forces and in Regional and National Interagency Coordination Committees (ICC). Country-level activities in support of immunization programmes will also be strengthened.

UNICEF has been requested to hold and manage on behalf of the Alliance the Working Capital Account of the Global Fund for Children's Vaccine. It is expected that US\$ 150 million from the Bill & Melinda Gates Foundation and an additional US\$ 150 million in matching funds from other donors will each year flow through this account. The projected increase in financial resources administered by UNICEF is 25%. This additional responsibility will give rise to increased interaction with a number of partners, donors and recipient countries, and a significant increase in the volume and complexity of related work-processes.

Additional resource requirements directly related to holding and managing the Fund Working Capital Account and for managing procurement of new and underused vaccines, on behalf of the Alliance, have been estimated and are outlined in this paper. These are costs that come on top of UNICEF's current activities and do not include the general organizational capacity-strengthening in immunization.

- The costs associated with the management of the Fund Working Capital Account at UNICEF Headquarters (Programme Division, Division of Financial and Administrative Management and the Programme Funding Office) have been estimated at US\$ 4.7 million for the five-year period.
- In relation to procurement of vaccines and supplies on behalf of the Alliance, and as a contribution to GAVI, UNICEF has agreed to waive the standard procurement services handling fee of 6%. The strengthening of Supply Division operations to coordinate forecasting, procurement and distribution of vaccines, immunization-related supplies and cold-chain equipment on behalf of the Alliance is budgeted at US\$ 7.2 million for the five-year period. UNICEF will allocate US\$ 2.7 million from other resources towards these activities. The request to the GAVI Board represents the balance of US\$ 4.5 million for the five-year period.

UNICEF's total request to the GAVI Board is US\$ 9.1 million for the period July 2000 – December 2004, which represents on average US\$ 2 million per year.

Following approval of this budget plan, administrative arrangements and monitoring procedures will be formalized by UNICEF and the Global Alliance for Vaccines and Immunization.

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## 1. UNICEF – the United Nations Children’s Fund

UNICEF was established by the United Nations in 1946 to meet the emergency needs of children in post-war Europe and China. In 1950, its mandate was broadened to address the long-term needs of children and mothers in developing countries everywhere. The agency became a permanent part of the United Nations system in 1953.

UNICEF maintains programmes in 161 countries. Some 86% of the organization’s 5600 posts are located in the field. There are eight regional offices and 125 country offices worldwide, as well as a supply operation in Copenhagen, a research centre in Florence and offices in Tokyo and Brussels. UNICEF headquarters is in New York.

Thirty-seven National Committees for UNICEF, mostly in the industrialized world, are nongovernmental organizations that support UNICEF in advocacy for children and fund-raising.

The Mission Statement of UNICEF is attached as annex 1.

In 1999, the total UNICEF expenditure was US\$ 1026 million. Of this, 91% was spent on programmes (US\$ 793 million for direct assistance to programmes and US\$ 141 million for programme support) and 9% went to management and administration. In that same year, 63% of UNICEF income came from governments. Most of the remaining 37% came from private sector fund-raising and through the sale of greeting cards.

UNICEF’s programmes are anchored in the Convention of the Rights of the Child (CRC), the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW), and the World Summit for Children (WSC) goals. UNICEF bases its programming process within a human rights framework adopted by the Executive Board in 1998.

As the international lead agency for children, UNICEF is spearheading efforts to broaden and strengthen alliances and build a global movement for children. The key elements for the creation of this movement are: the review of progress since the World Summit for Children in 1990; the Special Session on Children in September 2001; the process to mobilize and work with civil society; mobilization of young people; and Nelson Mandela and Graca Machel’s commitment to build a Global Partnership for Children.

The Global Partnership for Children aims at building alliances of influential decision-makers, governmental and nongovernmental, who have the power to shape national laws, policies, budgets, institutions and programmes or who influence how societies behave towards children and adolescents.

UNICEF’s activities are directed by an in-country programming process with national counterparts, based on an assessment and analysis of the situation of children and women. The results of this assessment form the basis for the national programme that is submitted to the Executive Board for final approval. This decentralized country-led process enables UNICEF to tailor its activities to the needs of children in their specific context.

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## **2. UNICEF commitment to GAVI and immunization**

Immunization has long been a cornerstone of UNICEF's health programmes. This commitment is best embodied in the efforts made in the 1980s and early 1990s by the organization and its partners to achieve Universal Child Immunization (UCI).

The greatest achievement of UCI was to raise immunization coverage to levels of 80% within a short amount of time. This contributed to significant reduction of mortality and morbidity in children and was in many countries the springboard for continuing efforts in child health and prevention.

Other major outcomes of UCI were to bring the importance and public health benefits of immunization programmes into the public and political eye and to increase the commitment of national governments and external donors.

UNICEF's strengths in the field of immunization and health include: a strong and long-standing partnership with governments, WHO and other allies; the unique role of country offices in assisting governments to plan, implement and monitor programmes; the capacity to mobilize political and public opinion at global, regional, national and subnational levels; the ability to raise funds; a two-fold programme approach with inputs both at policy and at operational level; cross-sectoral programming with special emphasis on systems strengthening and involvement of stakeholders and beneficiaries; and extensive procurement experience as the world's largest purchaser of vaccines for developing countries.

Around one third of UNICEF overall programme expenditures are allocated to child health programmes. UNICEF spends US\$ 100 million annually to support government efforts to immunize children, with an additional US\$ 10 million available this year for countries in special need of help.

The establishment of the Global Alliance for Vaccines and Immunization (GAVI) and the renewed emphasis on immunization within a context of accelerated human development and poverty reduction has prompted UNICEF to further reinforce its organizational and technical capacity. Taking into account all immunization-related initiatives (i.e. eradication of poliomyelitis, elimination of maternal and neonatal tetanus, control of measles, injection safety and elimination of vitamin A deficiency), UNICEF's capacity at headquarters, regional and country office level is being strengthened to effectively contribute to the achievement of ambitious and yet reachable global immunization goals.

Within the framework of GAVI, UNICEF will participate as a main partner in the shaping of the global agenda on immunization. UNICEF will be represented on the GAVI Board (and hold the chair in the second term), on the global Working Group, in the various GAVI Task Forces and in Regional and National Interagency Coordination Committees (ICC).

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UNICEF will specifically contribute to the common objectives of the partners in the Alliance in the following areas:

- ***Increase advocacy and communication in support of immunization***, including leading the Task Force on Advocacy and Communications and supporting implementation of the GAVI advocacy and communications strategic plan.
- ***Strengthen country-level activities***, including promotion of partnerships and assistance to national governments for improving management and delivery of immunization services, taking into account the changing operational context with administrative and health sector reforms, decentralization and private sector expansion.
- ***Promote programmatic and sustainable financing of immunization programs***, including expanding the Vaccine Independence Initiative initiated by UNICEF in 1992.
- On behalf of the Alliance, ***procure vaccines and related supplies***, including reinforcing the partnership with the Vaccine Industry.
- ***Fund-raise*** for immunization and health, aiming at raising an additional US\$ 1 billion over the next five years.
- ***Provide administrative support to GAVI***, including holding and managing the FUND Working Capital Account at UNICEF New York Headquarters and hosting the GAVI Secretariat at the Geneva Regional Office.

### **3. Management of the Fund Working Capital Account at UNICEF**

Thanks to an initial grant of US\$ 750 million from the Bill & Melinda Gates Foundation, a Global Fund for Children's Vaccines (the Fund) has been established and will be used to strengthen immunization systems in the poorest countries, procure vaccines and accelerate research and development of new vaccines against diseases such as malaria, tuberculosis and HIV/AIDS.

Upon recommendations from the GAVI Board, funds will be released from the Global Fund to a Working Capital Account to be used for procurement of vaccines, support to governments for strengthening their immunization services and for other purposes as determined by the Board.

While the GAVI Board makes recommendations on disbursement of funds from the Fund Working Capital Account, UNICEF has been requested to hold and manage it on behalf of the Alliance. It is expected that US\$ 150 million from the Bill & Melinda Gates Foundation and an additional US\$ 150 million in matching funds from other donors will each year flow through this account.

With a projected increase in funding volumes of 25%, holding and managing the Fund Working Capital Account entails a significant increase in workload for UNICEF. Extensive interaction with a number of partners, donors and recipient countries is also expected in relation to the management of the account.

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To be able to fulfil this new role in an efficient and timely manner and respond to the requirements of the Alliance, the institutional capacity of UNICEF will need to be strengthened. Separate units and work processes will not be established but the capacity of existing systems will need to be expanded. Following consultations with involved UNICEF divisions (Programme Division, Supply Division, Division of Financial and Administrative Management, and the Programme Funding Office), the additional requirements related to the management of the Fund Working Capital are detailed below.

### ***Programme Division (PD)***

#### **Roles and responsibilities**

The main responsibilities of the Health Section in the Programme Division with regard to immunization and implementation of GAVI-related activities are as follows:

- Provision of technical and programmatic guidance on immunization and health to UNICEF offices in 125 countries, 74 of which are currently eligible for support from the Fund.
- Technical consultation and coordination with partners, such as the WHO, the World Bank, the Bill and Melinda Gates Children's Vaccines Program (CVP) and BASICS II, and participation on the GAVI Working Group and Task Forces.
- In coordination with relevant UNICEF divisions, monitoring of programme implementation and utilization of allocations from the Fund Working Capital Account and preparation of proposals and reports to GAVI and to donors.

#### **Additional tasks and workload**

UNICEF will need to produce consolidated reports to the GAVI Board and to donors on the utilization and effectiveness of these funds. This will entail coordinating and consolidating reports from Supply Division, the Division for Financial and Administrative Management, and from up to 74 countries and other parties that will receive support from the Fund. Programme Division will also consolidate forecasting information from countries for vaccines and related supplies. Coordinating support from the Global Fund with efforts to expand the Vaccine Independence Initiative (VII) will also be a main priority.

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## Resource needs

The Health Section has already started to strengthen its capacity to support implementation of GAVI-related activities and acceleration of immunization and child health programmes. Four new professional posts have been established, two funded by UNICEF regular resources and two funded by other resources<sup>6</sup>. One of these posts funded with regular resources will, in addition to policy development and technical support, serve as liaisons with GAVI country coordination task forces. New posts have also been established with external resources in the Programme Division and in the Division of Communication to further strengthen the capacity in advocacy and programme communications.

In order for the Programme Division to adequately fulfil its obligations with regard to management and reporting on the Fund Working Capital Account, the Health Section will require one additional mid-level professional and administrative support. This staff would need qualifications and experience in financial management as well as in public administration.

## *Supply Division (SD)*

### Roles and responsibilities

In close collaboration with the WHO, who is responsible for commodity specifications and quality assurance, UNICEF Supply Division in Copenhagen handles coordination of forecasting, procurement and distribution of vaccines, immunization-related supplies and cold chain equipment. In 1999, the purchase volume (excluding related transportation) was US\$ 101 million for vaccines, US\$ 7 million for syringes and safety boxes and US\$ 4 million for cold chain equipment.

With regard to procurement on behalf of GAVI using funds from the Fund Working Capital, Supply Division will carry responsibilities in the following areas:

- Technical services, with staff working with WHO and suppliers on vaccines, injection supplies, safety disposal, cold chain and infrastructure – their specifications, sources, and quality.
- Contracting, with staff negotiating manufacturing capacity for products and maintaining industry relations in their implementation.
- Customer services (Africa, Asia, Middle East/CEE/CIS), with staff monitoring requisitions from internal and external customers and ensuring timely processing and delivery.
- Shipping arrangements, including safe receipt in countries.
- Processing of invoice and payments.

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<sup>6</sup> UNICEF, UNDP and UNFPA harmonized in 1996 their budget terminology. Regular Resources (RR) is the term used for voluntary contributions from donors that are co-mingled and untied. Other Resources (OR) is the term used for resources which are provided by donors for specific countries or regions and are meant to support specific projects or activities.

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The capacity of UNICEF SD to manage immunization operations has in the past year been strengthened to respond to the increased demand from immunization programmes, including from initiatives such as polio eradication and maternal and neonatal tetanus elimination. Additional staff has been recruited with own and other resources.

#### **Additional tasks and workload**

In the period 2000 to 2004 the additional vaccine volume to be procured with funds from the Fund Working Capital Account is projected to represent a value of US\$ 1 billion, making a total value of US\$ 1.5 billion worth of vaccines to be procured by Supply Division. This is a significant increase from current procurement levels.

Procurement of new and underused vaccines on behalf of the Alliance differs from the standard EPI vaccines and requires a higher degree of managerial complexity. Negotiations and management of contracts and agreements with the vaccine industry and suppliers will be key for the timely introduction of “GAVI vaccines” into national immunization programmes.

Procurement of auto-disable (AD) syringes is also projected to triple as early as this year and will continue to match the increased number of vaccines. Supply Division will need to maintain ongoing contact with manufacturers of AD syringes to be able to meet the expected demand from countries making the transition to this new injection technology. Cold chain in many countries will also need to be refurbished and replaced because of age and CFC environmental concerns.

#### **Resource needs**

UNICEF estimates that the current staff of five dealing with immunization at Supply Division needs to be increased in phases over the next 12 months to a total of 17. With regard to procurement on behalf of the Alliance with funds from the Fund, four additional international staff and six administrative support staff will be needed. This estimate is based on the expected increase of workload and recent experiences with the polio eradication initiative in balancing country needs and global availability of vaccines.

In terms of organization, a new Technical Services Centre for Immunization will be set up to provide specific focus to this area and execute on plans prepared by Programme Division and GAVI partners. The Contracting Group for Immunization will be expanded to handle the increased complexity and volume of contract and supplier management. Dedicated staff in the three Customer Services Centres will manage country requisitions. As such all additional staff in the Centres will directly relate to the increased work from GAVI and the Fund Working Capital Account.

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## ***Division of Financial and Administrative Management (DFAM)***

### **Roles and responsibilities**

The Division of Financial and Administrative Management (DFAM) is responsible for the global management of UNICEF's financial assets. With regard to management of the Fund Working Capital Account, DFAM is specifically responsible for:

- Receipt, management, and allocation of funds in the Working Capital Account – DFAM will review agreements and negotiate modifications as required. When funds are disbursed to countries or to other parties, DFAM will establish, modify and close Programme Budget Allocations (PBA), and dispose of any remaining funds in accordance with individual donor agreements. DFAM will ensure liquidity requirements are maintained and that in-flows from donors match current and anticipated out-flows through PBAs.
- Monitoring and reporting on utilization of funds – In coordination with Programme Division, the Programme Funding Office and Supply Division, DFAM will prepare periodic project and country level financial reports, consolidate financial results and indicators across countries and regions, and monitor usage of financial resources. DFAM will also prepare final financial reports with certification as and when required.
- Coordination with the GAVI Board and the GAVI Secretariat – DFAM will consult with the GAVI Secretariat regarding report obligations and processes, strategies for accumulating and reporting data by category and by country in disaggregated and consolidated formats for field and headquarters locations.

### **Additional tasks and workload**

The Fund Working Capital Account at UNICEF will bring a projected increase in funding volumes of 25% and PBA initiation and control volume increase of 10%. These volume increases are assumed based upon the US\$ 150 million per year from the Bill & Melinda Gates Foundation plus an expectation of up to another US\$ 150 million per year in matching funds from other donors.

DFAM does not anticipate a change of business processes for the GAVI initiative but will need to augment the capacity of systems and flows currently in use for existing projects.

### **Resource needs**

For the above-described increase in activities, DFAM will require three additional posts (budget, accounts and contributions), with periodic temporary administrative support. Supplemental electronic systems for tracking funding obligations, receipts, and flows will also be needed. This capacity strengthening needs to be done early on in order to ensure orderly flows of funds and information and to ensure that structures are in place and can meet evolving monitoring and reporting requirements.

In due time, additional consideration must also be given to the period after the end of the initiative, with a 6–9 month run-out period to finalize financial reports, close accounting records and archive documentation.

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## ***Programme Funding Office (PFO)***

### **Roles and responsibilities**

The Programme Funding Office has three critical roles with regard to GAVI and the Fund:

- Liaison with governments regarding funding for immunization, including GAVI/the Fund and UNICEF. Major link with the GAVI Secretariat and the Fund in this regard is primarily through the Fundraising Task Force and secondarily through the Advocacy Task Force.
- Liaison with the US Fund for UNICEF, the Gates Foundation, PATH/CVP, and the eventual staff of the Fund regarding the U.S. Strategic Fundraising Plan. PFO contributes to this plan, particularly on the governmental side.
- Set up and management of the individual contributions generated by the Fund, the Fund Working Capital Account and PATH/CVP. This will include proper recording of contributions, creation and maintenance of contribution files, handling of reporting, extensions, and eventual close-out of contributions.

### **Additional tasks and workload**

The creation of GAVI and the Fund requires additional work by PFO. In advance of actually receiving funding, PFO already has devoted considerable time and resources to educating our governmental partners about GAVI. Briefings for the GAVI Secretariat with government donors have also been organized and followed-up with such governments in pursuit of funding.

Upon approval of country allocations by the GAVI Board, PFO will be responsible for the set up and maintenance of funding files related to GAVI. While it is not expected that all GAVI related funding will come through UNICEF, a volume and workload increase is expected.

### **Resource needs**

In order to ensure an appropriate level of consistent outreach and liaison with donors about GAVI and the Fund, and maintenance of the GAVI-related contributions, PFO will require at minimum a mid-level programme funding officer and administrative support.

## ***4. Budget requirements 2000–2004***

The incremental costs to UNICEF of tasks directly related to support to GAVI and the Fund Working Capital Account are estimated to be US\$ 15 million for the period July 2000 to December 2004. These are costs that come on top of UNICEF's current activities and do not include the general organizational capacity-strengthening in immunization.

The request to the GAVI Board covers the costs to UNICEF that are directly related to holding and managing the Fund Working Capital Account at headquarters and managing procurement of new and underused vaccines, on behalf of the Alliance.

- The costs associated with management of the Fund Working Capital Account at UNICEF Headquarters (Programme Division, Division of Financial and Administrative Management and the Programme Funding Office) have been estimated at US\$ 4.7 million for the five-year period.
- In relation to procurement of vaccines and supplies on behalf of the Alliance, and as a contribution to GAVI, UNICEF has agreed to waive the standard procurement services handling fee of 6%. The strengthening of Supply Division operations to coordinate forecasting, procurement and distribution of vaccines, immunization-related supplies and cold-chain equipment on behalf of the Alliance is described above and budgeted at US\$ 7.2 million. UNICEF will allocate US\$ 2.8 million from other resources towards these activities. The request to the GAVI Board represents the balance of US\$ 4.5 million over the five-year period.

The total request for the period July 2000 – December 2004 is US\$ 9 122 700, which represents an average of US\$ 2 million per year. Allocations are summarized in the tables below.

**Table 1: Budget requirements 2000-2004, per division (thousand US dollars)**

HQ Divisions	2000	2001	2002	2003	2004	TOTAL
Supply Division	558.9	902.2	947.2	1,018.5	1,040.7	<b>4,467.5</b>
Programme Division	149.0	248.6	261.1	274.4	288.4	<b>1,221.5</b>
DFAM	100.0	313.9	372.3	414.1	471.9	<b>1,672.2</b>
Programme Funding Office	193.6	363.2	381.7	401.2	421.8	<b>1,761.5</b>
<b>TOTAL</b>	<b>1,001.5</b>	<b>1,827.9</b>	<b>1,962.3</b>	<b>2,108.2</b>	<b>2,222.8</b>	<b>9,122.7</b>

DFAM: Division of Financial and Administrative Management

**Table 2: Budget requirements 2000-2004, per category (thousand US dollars)**

HQ Divisions	2000	2001	2002	2003	2004	TOTAL
Posts (8)	404.0	914.7	970.4	1,029.4	1,091.9	<b>4,410.4</b>
Support Staff (9)	301.6	657.1	687.1	718.5	751.4	<b>3,115.7</b>
Contractual Work	100.0	60.0	107.0	133.5	175.0	<b>575.5</b>
Travel	121.0	173.5	173.6	176.3	179.1	<b>823.5</b>
Operating Expenses	15.2	13.8	14.1	14.5	14.8	<b>72.4</b>
Furniture and Equipment	59.7	8.8	10.1	36.0	10.6	<b>125.2</b>
<b>TOTAL</b>	<b>1,001.5</b>	<b>1,827.9</b>	<b>1,962.3</b>	<b>2,108.2</b>	<b>2,222.8</b>	<b>9,122.7</b>

DFAM: Division of Financial and Administrative Management

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## 5. Reporting

Following approval of the budget plan by the GAVI Board, specific administrative arrangements and monitoring procedures will be formalized between UNICEF and GAVI.

**UNICEF will prepare and present to the GAVI Board annual reports, including activities and expenditures for the previous year, and as far as possible, performance in relation to specific targets.**

### **The Mission of UNICEF**

UNICEF is mandated by the United Nations General Assembly to advocate for the protection of children's rights, to help meet their basic needs and to expand their opportunities to reach their full potential.

UNICEF is guided by the Convention on the Rights of the Child and strives to establish children's rights as enduring ethical principles and international standards of behaviour towards children.

UNICEF insists that the survival, protection and development of children are universal development imperatives that are integral to human progress.

UNICEF mobilizes political will and material resources to help countries, particularly developing countries, ensure a "first call for children" and to build their capacity to form appropriate policies and deliver services for children and their families.

UNICEF is committed to ensuring special protection for the most disadvantaged children – victims of war, disasters, extreme poverty, all forms of violence and exploitation and those with disabilities.

UNICEF responds in emergencies to protect the rights of children. In coordination with United Nations partners and humanitarian agencies, UNICEF makes its unique facilities for rapid response available to its partners to relieve the suffering of children and those who provide their care.

UNICEF is non-partisan and its cooperation is free of discrimination. In everything it does, the most disadvantaged children and the countries in greatest need have priority.

UNICEF aims, through its country programmes, to promote the equal rights of women and girls and to support their full participation in the political, social, and economic development of their communities.

UNICEF works with all its partners towards the attainment of the sustainable human development goals adopted by the world community and the realization of the vision of peace and social progress enshrined in the Charter of the United Nations.

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# Annex 7.1

## GAVI Board composition

*Adopted by the GAVI Board, 14 June 2000*

<b>Partner Organization</b>	<b>no. of seats</b>
UNICEF	1
The World Bank	1
WHO	1
The Bill & Melinda Gates Foundation	1
OECD Country Governments	3
Developing Country Governments	2
OECD Country Industry	1
Developing Country Industry	1
Foundations	1
Research and Development Institutions	1
Technical Health Institutions	1
Nongovernmental Organizations	1
Chair	1
<b>Total Number of Board Seats</b>	<b>16</b>



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# Annex 7.2a

## GAVI Guiding Principles

*Presented by Tore Godal, GAVI Secretariat*

The basic elements of the Global Alliance for Vaccines and Immunization are currently contained in three different documents:

- a) GAVI/99.01 Meeting of the Proto-Board
- b) GAVI/99.02 First Board Meeting
- c) GAVI/00.01 Second Board Meeting

To comply with the request made by the Board during its second meeting, the Secretariat has prepared the attached document. This document presents in a comprehensive way the separate provisions, which appear in the three documents mentioned, without modifying their substance.

It contains also certain suggestions, in view of clarifying certain existing provisions.

It has to be observed that the document presented is only related to the institutional and operational arrangements applicable to the Alliance and does not tackle the financial arrangements related to the Fund.

### **Observations on the question of juridical personality**

From the different documents related to the Alliance, it is obvious that the Alliance, as such, does not possess the juridical personality. This means, in practical terms, that the Alliance does not have the capacity to contract, to acquire and dispose of immovable and movable property, and to institute legal proceedings. The members of the different organs of the Alliance (Board, Working Group, Secretariat) do not have either the legal capacity to represent the Alliance, to speak on its behalf or to legally commit the Alliance.

The solution, which has been found so far, “the option one” has been to put the Secretariat of the Alliance “under the umbrella” of the host organization, UNICEF. That arrangement permits the Alliance to benefit from the systems of the host institution in particular concerning the facilities and privileges. It implies the conclusion with the host institution of an administrative arrangement defining the relations existing between the two institutions. But this arrangement does not give to the Alliance the legal “visibility” which it would have if the judicial personality were recognized.

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Another possibility “the option two” would be to obtain the judicial personality for the Alliance itself. For that, it would suffice to create a nongovernmental organization in the form of an Association in Switzerland under article 60 and sq of the Swiss civil code. That would require certain formalities such as the drafting of statutes and their deposit with a notary in Geneva. The “legal visibility” would be then obtained. The Alliance, as such, could contract purchase etc., BUT, unless a special host agreement with Switzerland is concluded, the Alliance would not enjoy any privileges and immunities, in particular regarding tax exemption, customs duties, etc.

A third option, “the option three” would be to create through the conclusion of a memorandum of understanding a sort of special Programme, similar to those existing in certain organizations (such as the TDR programme or the onchocerciasis programme in WHO) of which the executing Agency could be for example UNICEF. As such the Alliance would have a large visibility without obtaining the juridical personality, but would benefit the juridical personality of UNICEF.

The GAVI Board at its 3<sup>rd</sup> meeting in Oslo, 13–14 June adopted option one and the attached guiding principles.

The guiding principles outlined below do not conflict in any way with the status referred to as option one.

## **Guiding Principles of the Global Alliance for Vaccines and Immunization**

### ***Section I – Description of GAVI***

#### **Paragraph 1 – *Mission***

The Global Alliance for Vaccines and Immunization (hereinafter called “the Alliance”) has been created to save children’s lives and protect people’s health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries.

#### **Paragraph 2 – *Strategic objectives***

The strategic objectives of the Alliance are the following:

- a) To improve access to sustainable immunization services.
- b) To expand the use of all existing cost-effective vaccines.
- c) To accelerate the development and introduction of new vaccines.
- d) To accelerate research and development effort for vaccines and related products specifically needed by developing countries.
- e) To make immunization coverage an integral part of the design and assessment of health systems and international development efforts.

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### **Paragraph 3 – Partnership**

The Alliance is a network of international organizations, industrialized and developing countries, technical agencies, research and development agencies, industry, foundations, non governmental organizations and other entities which have expressed their interest in its mission and objectives by notifying the Executive Secretary. The members of the Alliance are called “the Partners”.

### **Section II – Framework**

#### **Paragraph 4 – Mechanisms**

The mechanisms of the Alliance are:

- a) The Partner’s meeting
- b) The GAVI Board (hereinafter called “the Board”)
- c) The Working Group
- d) The Secretariat

#### **Paragraph 5**

5.1. The Partner’s meeting shall consist of all the members of the Alliance

5.2. The Partner’s meeting will:

- a) exchange views on matters related to the Alliance in particular in relation to the improvement of the immunization services.
- b) constitute a forum within which the selection of the respective representatives of each group on the Board and, as the case may be, in the working group, will be made. All proposed candidates, except for those mentioned under paragraph 6.1.1.a) will be subject to a consultation process, led by the Chair either of the Board or of the working group whichever is applicable. After consultation, the Chair of the Board or of the working group will decide whether there is a general agreement on the selection. If there is no consensus, the Chair will ask the group to come forward with an alternative candidate who will then have to go through an identical consultation process.
- c) Consider any other matter referred to it by the Chair of the Board.

5.3 The Partner’s meeting will normally take place every two years.

The provisional Agenda will be prepared by the Executive Secretary in consultation with the Working Group and the Chair of the Board.

The Partner’s meeting will select its President amongst its members for the duration of the meeting.

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## **Paragraph 6 – *The Board***

### **6.1 Composition:**

6.1.1 The Board is composed of members from amongst the Partners as follows:

a) One representative of each of the following members:

The Bill and Melinda Gates Foundation

UNICEF

The World Bank

WHO

The term of these members will be two years renewable.

b) One representative of each of the following groups of the other partners namely:

Foundations

Industry from the developing countries

Industry from the OECD countries

Research Institutions

Technical Health Institutions

Nongovernmental organizations

c) Two representatives of the group of the developing countries.

d) Three representatives of OECD countries.

6.1.2 Attendance of board meetings by Board members will be limited to their designated representatives, without the possibility of their replacement by alternates in the case of absence.

6.1.3 The Executive Director of UNICEF, the President of the World Bank and the Director-General of WHO are currently considered as members *ex officio*.

6.1.4 The Board might change the composition of the Board without exceeding the limit of fifteen members including the Chair.

6.1.5 To ensure an equitable rotation amongst the representatives of the members of the Board mentioned under paragraph 6.1.1.b) c) and d), their terms of office will be normally two years, non-renewable. However to secure continuity, an extension of one year of the first mandate of half of these members will be made to permit a staggering of terms. The non-renewable members will hold their seats until their successors are elected.

### **6.2 Functions:**

6.2.1 The Board is the highest body of the Alliance which provides a forum for decision making on common objectives and strategies.

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### 6.2.2 The Board will

- a) Review, approve and update joint objectives and milestones.
- b) Review progress in achieving objectives and milestones.
- c) Commit resources in order to achieve objectives and milestones.
- d) Review and approve the proposed action plans of the Alliance.
- e) Note and monitor the commitments of Partners to undertake certain strategies and activities.
- f) Identify gap and areas needing increased attention and resources.
- g) Approve budgets of the Secretariat and any task force that might be established by the Board.
- h) Review the annual financial statement prepared by the Executive Secretary. The Secretariat will be subject to audit review by the office of the internal audit of the host organization.
- i) Contribute, through its members, to fundraising and advocacy activities.
- j) Nominate the Executive Secretary and submit its name to the host organization for appointment.
- k) Identify other potential partners.
- l) Authorize the release of funds for projects from the working capital account.
- m) Consider and approve any amendment to the guiding principles.
- n) Consider such other matters related to the Alliance as may be referred to it by the Executive Secretary or the Working Group.

### 6.3 Operation

- 6.3.1 the Board will meet as the need arises, in principle twice a year for a two day session;
- 6.3.2 the provisional Agenda will be prepared by the Executive Secretary in consultation with the Working Group and the Chair;
- 6.3.3 observers may be invited to attend the Board's meeting or part of it upon invitation from the Chair. The Observers will have the right to participate, without a vote, in the deliberation of the Board;
- 6.3.4 the Board will select from amongst its members a Chair whose term will be two years non-renewable;
- 6.3.5 the Executive Secretary will be the Secretary of the Board;
- 6.3.6 the Board shall normally take its decision by consensus. Nevertheless should a vote be required each member will have one vote only, the ex officio members, if present, voting for their respective organizations;
- 6.3.7 the decision taken by the Board will not be considered as binding upon the organizations and will not override their respective governing bodies;

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## **Paragraph 7 – *The Working Group***

### **7.1 Composition**

The composition of the Working Group needs to be skill based and linked to implementation partners and current priority activities.

The Working Group is composed as follows:

- a) A representative of each of the members of the Board mentioned under paragraph 6.1.1. a).
- b) One representative of the group of the OECD countries.
- c) One representative of the group of the developing countries.
- d) One representative from R&D institutions.
- e) One representative from industry.
- f) The President of the Global Fund for Children’s Vaccines.
- g) The Executive Secretary.

The partners to be represented on the Working Group will be determined by the Board. The composition of the Working Group will be periodically reviewed by the Board, which might change its size without exceeding the limit of ten members.

### **7.2 Functions**

The Working Group will facilitate the implementation of the decisions and policies of the Board through:

- a) Translating the Alliance’s work plans into Partners work in view of their implementation by them.
- b) Developing work plans and assessing progress on work plan.
- c) Making proposals to the Board as provided for in these guiding principles or on its own initiative.
- d) Performing any other functions entrusted to it by the Board.

### **7.3 Operation**

- a) The Working Group will meet as the need arises, in principle four times a year and hold periodic teleconference.
- b) The provisional agenda will be prepared by the Executive Secretary.
- c) The Working Group will be chaired by one of its members selected by it.
- d) If appropriate and for specific topics, the Chair, in consultation with the Working. Group, may invite external person to participate without vote in the deliberation thereon.
- e) The Working Group will normally take its decision by consensus.
- f) The Executive Secretary will report regularly to the Board about the discussions of the working group.

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## **Paragraph 8 – *The Secretariat***

### **8.1 Organization**

- a) The Secretariat will be led by the Executive Secretary.
- b) The Secretariat shall comprise technical and administrative staff as the Board may decide.
- c) The Executive Secretary will be responsible for designating the staff of the Secretariat following the procedure of the host organization.
- d) The condition of service of the staff will be those of the host organization.

### **8.2 Functions**

In close collaboration with the Working Group, the Secretariat will:

- a) Develop for the Board's approval a consolidated work plan based on the partner's work plans and commitments, including plans and budgets for the Secretariat; the Working Group and any Task Force established by the Board.
- b) Be responsible for the operations of these Task Forces.
- c) Coordinate and monitor the progress of activities.
- d) Evaluate progress towards the Alliance milestones.
- e) Coordinate the development of the Partners' resource mobilization strategies.
- f) Provide the administrative support to the Board, the Working Group and the Partner's meeting.
- g) Disseminate information relating to the Alliance to the Partners.

### **8.3 Operation**

- a) The Secretariat will be housed in the premises of UNICEF in Geneva.
- b) The Secretariat will be exclusively funded by the contributions of the Partners.
- c) The Secretariat will not raise funds for its own activities.

## ***Section III – Final provisions***

### **Paragraph 9**

While the Alliance, as such, does not possess the juridical personality, the Executive Secretary, as the head of the Secretariat, is liable towards the Partners for all the acts performed by him or herself or on his/her behalf in his/her official capacity. In this respect, any dispute related to the exercise of these activities shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the international chamber of commerce. The parties shall accept the arbitral award as final.

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**Paragraph 10**

Any Partner of the Alliance may withdraw from participation by notifying the Executive Secretary of its intention to do so. Such notification will take effect six months after its receipt.

**Paragraph 11**

The Board might decide on the dissolution of the Alliance by a two-third majority of its members.

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# Annex 7.2b

## African perspectives on GAVI<sup>7</sup>

*Presented by Lomamy Shodu, Zimbabwe Ministry of Health*

The development of GAVI and steps for its implementation of concept have occurred over a short period of time. Therefore, not much time was allowed for necessary inputs from regions and countries. In order to be proactive and seize the opportunities offered by this initiative, WHO/AFRO and UNICEF/WCAR, have held an informal meeting on GAVI in Abidjan, Côte d'Ivoire from 14 to 15 April 2000. The objectives of this meeting were: (i) clarify GAVI processes and working mechanisms, (ii) define how African expertise in EPI should contribute to GAVI decision-making processes and activities at global, regional and country levels and (iii) define how GAVI should contribute to sustaining immunization systems and disease control in Africa.

Below is a summary of the main issues and actions proposed by the group:

### **Communication**

Communication problems and some confusion have arisen in the understanding of what GAVI is and how it operates. This was caused primarily by the fact that the GAVI concept was defined and launched over a short period of time. Additional communication problems have included insufficient or inadequate information flow and lack of consistency of the messages conveyed by the GAVI partners.

### ***Proposed actions***

- Board and Working Group should substantially increase the amount of information sharing, through face-to-face communication, with regional and country staff.
- All GAVI documents should be timely translated into French.

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<sup>7</sup> Abstracted from the Position Paper of the 14-15 April Abidjan meeting to discuss GAVI, attended by regional and country representatives of UNICEF and WHO, the African Development Bank, the Association for Preventive Medicine (AMP). Representatives of the GAVI Working Group and Board were also in attendance.

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## **GAVI Board, working group and task forces**

Regional and country staff feel that GAVI does not properly address some issues specific to the region.

### ***Proposed actions***

- Establish a regional GAVI working group for Africa to ensure interactions with the global working group and promote the implementation of GAVI, taking into consideration ongoing EPI regional initiatives
- Regional representation in the global GAVI Working Group is also suggested.
- The GAVI Board should hold some of their meetings in Africa

## **Global Fund for Children's Vaccines (the Fund)**

The method for allocating funds from the subaccount for immunization services needs to be more clearly determined. The fixed value of the shares at US\$ 20 per child for each country does not consider the real costs of child immunization in the different countries. (The cost of vaccinating a child in Chad or Niger is much higher than in Zimbabwe). Furthermore, GAVI does not appear to have mechanisms for addressing the excess mortality caused by some regional priority diseases such as measles.

### ***Proposed actions***

- Mechanisms for channelling the funds to countries should take into account the Regional experience with the Polio Eradication Initiative. Funds should be disbursed through a lead agency (and not through channels such as ICCs).
- The possibility of having several values for the share based on the country population and/or GNP with a scaling up mechanism should be considered.
- Switching to AD syringes for all EPI vaccines should be conditionality to accessing GAVI funds.
- GAVI should consider establishing a fourth subaccount for disease surveillance and control of EPI diseases to help maintain the gains of AFP surveillance and lower measles and yellow fever disease burdens.

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## **Sustainability/ownership**

Past experience to improve EPI and immunization coverage have shown that these were difficult to maintain after the withdrawal of the financial support from donors.

### ***Proposed actions***

- Review of country applications to the Global Fund should include an indicator of government financial commitment to EPI (e.g., existence of a budget line on EPI in the annual national budgets).
- A stronger link must be established between GAVI and the Highly Indebted Poor Countries initiatives (HIPC).
- ICCs must be strengthened, with strong and high level involvement of the officials of the ministries of health and adequate support from WHO and UNICEF staff.

## **Data management**

Although they constitute the basis for countries assessment and evaluation, current immunization data are not reliable, there is therefore a need to improve EPI data management. District populations and disease burden need to be established in a more accurate way in most countries in the region and disease impact should be considered as an evaluation criteria.

### ***Proposed actions***

- Urgently address the improvement of EPI data management in the countries, from the points of data collection (health facilities) to the central level.
- Support disease surveillance efforts to monitor the impact of the immunization effort of the burden of diseases.
- Support research efforts to establishing country disease burden.

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# Annex 7.3

## Overview of the operations function in the GAVI Secretariat

*Presented by Umberto Cancellieri, GAVI Secretariat*

### **A. Introduction**

1. The purpose of this document is to provide a brief overview of the operations function in the GAVI Secretariat to the GAVI Board members, and to obtain their endorsement of this arrangement. This paper will not cover issues related to the management of the Global Fund for Children's Vaccines, which will be covered in other documents.
2. At the meeting of the GAVI Proto-Board in Seattle in July 1999, UNICEF offered to host the GAVI Secretariat in the UNICEF Office for Europe in Geneva. This offer included the utilization of the UNICEF infrastructure and systems.
3. It is proposed that the Secretariat follow the UNICEF rules and regulations for its administrative, financial and human resource management. However, as the Alliance is a unique and separate entity, there may be a need to make adaptations or exceptions to these rules and regulations, in order to meet particular needs of the Alliance. In such cases, the Executive Secretary will present a proposal to UNICEF and the Working Group for endorsement. Such exceptions will be reported to the Board in a "Log of Administrative adaptations and exceptions for the GAVI Secretariat".

### **B. Work Plan and Working Group**

4. The Secretariat will collaborate with the Working Group to prepare an annual work plan, to be submitted for approval to the GAVI Board. The members of the Working Group will be responsible for implementation of the plan.

### **C. Financial Management**

5. The GAVI Board has agreed that each member of the Alliance will contribute US\$ 300 000 annually for the functioning of the Secretariat. The Executive Secretary is accountable for the utilization of these funds according to the appropriations approved by the GAVI Board.
6. The funds are administered as a trust account within UNICEF and therefore are not considered to be income to UNICEF. Funds are disbursed through UNICEF Geneva at the request of the Executive Secretary.
7. To facilitate management of the funds, it is proposed to pool the contributions into one reporting, financial and auditing system.

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8. The accounting unit is the United States dollar. The equivalent in United States dollars of other currencies is established on the basis of the United Nations operational rates of exchange.
  9. Expenditures are accounted for on an accrual basis, except for those relating to staff entitlements which are accounted for on the basis of cash disbursements only. UNICEF has agreed that the normal Cost Recovery for incremental indirect costs will not be levied against the Secretariat funds. This applies to the various financial transactions, including bank charges.
  10. The UNICEF Comptroller is the only authorized source to provide a certified financial report. This would be done as soon as the UNICEF books are closed. Certified financial reports would be available within 60 days of the closing of the books for the financial year. As soon as these reports are released, the Executive Secretary will submit them for approval to the Board. The Secretariat will be able to access utilization reports at any time.
  11. It is proposed to follow a fiscal cycle starting on 1 January of each year; budgets will therefore be approved by the GAVI Board in the Autumn session preceding the new fiscal year.
  12. The Executive Secretary will regularly communicate to UNICEF concerning the Table of Authority, for the approval of GAVI transactions.

#### **D. Administrative Management**

13. Procurement of office supplies and furniture, handling of official travel are performed according to UNICEF rules and regulations, within budgetary appropriations.

#### **E. Human Resources Management**

14. The GAVI Board approved six posts for the Secretariat. Staff members working in the Secretariat are basically working on two types of UNICEF contracts (Fixed-term appointments and on a reimbursable loan basis).
15. The Executive Secretary is to be appointed by the Executive Director of UNICEF based on Board-directed selection process. The Executive Secretary is responsible for the appointment of the Secretariat staff. UNICEF recruitment procedures will be followed with regards to advertisement of posts. In the case of professional staff, a review panel will include at least two members of the Working Group.
16. UNICEF Special Service Agreements contracts are issued for consultants.

#### **F. Audit**

17. The Secretariat will be subject to Internal Audit review by the Office of Internal Audit of UNICEF. Audit reports will be addressed to the UNICEF Executive Director with copies to the Executive Secretary. The UNICEF Executive Director will then inform the Board.

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**G. Management Facilities Provided by UNICEF.**

18. The Secretariat is grateful to UNICEF for hosting its offices within the Regional Office for Europe in Geneva and for being able to benefit from the Common Services facilities provided by its IT, Operations and HR Sections.
19. The Secretariat will absorb the cost of telephone calls and the purchase of its equipment and office supplies.
20. Once the Board endorsement is received, it is proposed that the Chair of the GAVI Board and the UNICEF Executive Director formally signs this Overview of the Operations Function in the GAVI Secretariat.



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# Annex 8

## GAVI Partners' Meeting – Noordwijk, the Netherlands November 2000

### Provisional programme

*Presented by Tore Godal, GAVI Secretariat*

#### **Saturday 18**

Gates Children's Vaccine Program  
SAC meeting

#### **Sunday 19**

Morning: Meeting of Task Forces  
Afternoon: 12:00 – 18:00 GAVI Board meeting  
Evening: Dinner with Board members  
and other invited guests

#### **Monday 20**

Morning: Opening addresses  
GAVI progress and challenges

Els Borst-Eilers  
Gro Harlem  
Brundtland

Key note addresses

- country perspectives of GAVI
- research and development
- field research towards a better immunization system
- sustainable financing

A Health Minister  
from a GAVI  
supported country

Afternoon:

- Address from the European Union
- Meeting of constituencies
- Report from constituency meetings
- Outlook of GAVI – future dreams, realities and global participation

Evening: Reception and dinner offered by  
Dutch Ministry of Health

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## **Tuesday 21**

**Morning:** “Controversial” issues

- technology transfer
- capacity building

**Afternoon:** The way ahead: discussions on

- country activities
- research and development
- coordination, building network
- information exchange

## **Wednesday 22**

Meeting of the Working Group

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# Annex 9:

## List of participants

### Chair

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### Developing countries

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<sup>B</sup> Board Member  
<sup>W</sup> Working Group Member  
<sup>o</sup> Observer

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## Foundations

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## Industry

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## Ministries of health/technical agencies of OECD countries

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- 
- <sup>B</sup> Board Member  
<sup>W</sup> Working Group Member  
<sup>O</sup> Observer

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## Agencies of international cooperation, OECD countries

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