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First Board Meeting

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Executive summary

Introduction

The meeting was held at UNICEF House in New York on 28th October 1999. Ms Carol Bellamy Executive Director of UNICEF welcomed Board members and observers to the meeting.

Dr Gro Harlem Brundtland, Director General of WHO and Chair of the Board emphasized in her introductory statement that vaccines and immunization are key tools in breaking the vicious circle between health and poverty (Annex 1).

She outlined the main challenges of GAVI as follows:

- improve the coverage of immunization building on the lessons from the Polio initiative;
- reduce the gap between the number of vaccines used for children of the rich versus the poor countries;
- find new tools to secure R&D for diseases prevalent in poor countries such as malaria and HIV.

Dr. Brundtland stressed the urgency of filling these gaps.

The Board approved the recommendations of the Proto-Board meeting held in Seattle 12-13 July as a basis for GAVI's operations. As outlined in that report, decisions by GAVI Board would not over-ride the authority of the Governing Boards of each individual partner organization.

Global fund for children's vaccines

The GAVI Board adopted the following basic principles of the Global Fund for Children's Vaccines:

- the fund is considered as an essential part of GAVI to fulfil its mission;
- the basic structure and operations of the Fund approved by the Board have been set out in Annex 2;
- the first sub-account, "procurement of new vaccines and safe injection equipment will be used for the purchase of newer vaccines for the poorest countries based on proposals from their governments. The guidelines for use of this sub-account are set out in Annex 2.

The Board expressed its sincere gratitude to the Bill and Melinda Gates Foundation which allowed the fund to be established with an initial grant of $750 million over 5 years.

The Board stressed the need for developing sustainable financing instruments of vaccine procurement. The development and implementation of multi-year immunization plans within the context of health sector development and action to reduce poverty lead by national governments was emphasized as key to secure sustainable financing, including external resources.

Vaccine procurement

GAVI seeks to achieve a balance between three objectives:

- prices that are affordable to governments;
- adequate investment in capacity to supply global needs; and;
- private investment in research and development of high priority vaccines for developing countries.

Therefore,

- GAVI acknowledges and supports the fact that different markets have different effective prices, and that;
- the poorest country segment should have the lowest effective price.

The current procurement strategy of GAVI addresses the procurement of the vaccines and the target countries set out in Annex 2. This procurement strategy:

- seeks the lowest effective price for the purchase of these vaccines for the eligible countries;
- is based on the principle of open, competitive tendering through UNICEF Supply Division;
- will explore a competitive negotiation mechanism with producers of new vaccines to help bring these vaccines to the poorest populations at the earliest possible time;
- the GAVI Board expresses its gratitude to the pharmaceutical industry for making efforts to make these vaccines available at the lowest possible prices.

Launch

The Board approved the GAVI launch to take place at Davos, Switzerland, in the context of the World Economic Forum on 31st January 2000 in the afternoon.

The Launch will consist of a panel presentation by key representatives of the GAVI Board followed by a press conference.

Dates and place of next meetings

The next Board meeting is planned to take place at Davos on 31 January 2000 in the morning. The following Board meeting is planned to take place at WHO Geneva on 13 and 14 June 2000.

Acknowledgements

The Board acknowledged the excellent presentations made by Dr. Mark Kane and Mr. Piers Whitehead. Their overheads and the discussion paper prepared by Mr. Whitehead are attached (Annexes 3.1 to 3.3).

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Annex 1: Introduction by Dr. Gro Harlem Brundtland, Director-General, World Health Organization

First Board Meeting of the
Global Alliance for Vaccines and Immunization
28 October 1999

Ladies and gentlemen,

A process of hard work is taken to a point of departure: I welcome you all – members of the GAVI Board - to this meeting. It is a first.

It is, however, not the first time that we meet in our commitment to global health. I see around this table many familiar faces - people dedicated to find new and innovative solutions and to harness existing knowledge to serve people in need all over the world. Let us agree – it is the commitment of people and their institutions that make change.

Some may argue that it is not the first time partners come together for the cause of vaccines and immunization. And they are right. But each generation will go for approaches tailored to the needs of their times. The need for vaccines – new as well as established ones – is not new. But we still have to understand what our times require of new solutions – contributions from new partners – fostering of new and old partnerships – new ways of financing. In short a renewed ability to update our mental maps and act accordingly.

All that has led us to this meeting today. A broader alliance. New partners. New commitment. An exciting agenda. And a lot to do.

So why an alliance? Because it is exactly what the name implies: an alliance, which will hold us and the constituencies we represent accountable for our individual contributions to the actions that we, as individual shareholders, commit to undertake. An alliance which will help us to deliver more than each of us can do if we go it alone. An alliance where the glue is the commitment we all bring. The merger of our comparative advantages.

My personal driving force in this work is the conviction that improved health fosters development and reduces poverty. If a child is free from disease then it thrives, it develops and it matures to harvest the potential that society has afforded. If a child is sick, we all know that the opposite happens. When grown-ups get sick they cannot work and both the family and the society suffer. Sick people lose energy, initiative and money. They also lose their dreams - and all this is more devastating for the poor than for those better off.

Poor populations suffer from a disproportionately large burden of disease, such as those caused by infections. That is why we must give the highest priority to alleviating the brunt of disease, disability and death that poor people suffer.

If we take stock of the current situation then we can see that there are so many new opportunities, so much commitment and so many new partners that can contribute to our endeavours.

Just look to the current initiatives to link debt relief with renewed investment in the social sector. When the richest nations decided to embark upon a new programme for debt relief to the highly indebted poor countries, there was an underlying current that, this time, a new agenda should be put in place: an agenda of social development and poverty reduction. Resources freed from debt relief should go to strengthen the health and education component. I call this a breakthrough, although the results are yet to be seen. If things go well we will have yet another financing tool to help us invest in cost-effective health interventions especially among the poor – and on the health agenda, immunization ranks high on that list.

Let me bring us to our task today.

- We do know that poor people are affected by disease to a greater degree than richer people
- We know that children are those most affected
- We know that infectious diseases are mainly responsible for this excessive disease burden.

So, first we must focus our highest attention to those diseases that cause excessive morbidity and mortality. Second, we must do it in such a way that we get most health for the money we invest. And third, old wisdom has it that prevention is better than cure. We must therefore choose a small range of interventions that protect against diseases with a high disease burden, which are highly cost-effective and give us the highest returns in terms of good health.

So in short, vaccines and immunization are key.

The Expanded Programme on Immunization has rightfully been applauded for many successes in the past. But can we do more? Yes, we most definitely can. Three major gaps have emerged:

First - coverage with the traditional six vaccines in developing countries has stagnated since 1990. While the world average has remained at about 80%, sub-Saharan Africa is just over 50% and it has only increased with a few points in the last five years. And national averages hide discrepancies between regions and within urban and rural populations. Immunizations reach more children in poor countries than any other health service, but if we map poverty we also identify areas with low coverage. And we can do more to reach the unreached. The polio initiative has shown us some of the ways. We must draw on these lessons and put them into use.

We also need to improve the quality of our data so that we can direct our strategies with higher precision. In some countries we know that coverage data do underestimate the realities - in others the reverse is true.

Secondly - it has taken us much too long to introduce the newer vaccines such as those against haemophilus influenzae pneumonia and hepatitis B. The fact is that the vaccine gap - the number of vaccines routinely used in national immunization programmes in the rich world compared to those provided in the poor countries - is widening. Eleven vaccines today in the US but only six in Malawi. We must reduce this gap!

Thirdly - investment in research and development for those diseases that are prevalent in the poor countries, but for which no market exists in the industrialised world is seriously lacking. Just think of the HIV and malaria vaccines that we desperately have needed for years. We must find new tools to finance and stimulate such research!

These three gaps will be the main challenges for GAVI.

We are here today because we agree on a set of shared objectives and we all contribute to a joint action plan. You are all familiar with the parameters that were agreed upon by the Proto-Board in July. It is our responsibility to translate these parameters into action.

GAVI has also come into being because we want to embrace a broader partnership. Industry is here and I hope that this new example of private-public partnership will show that we can do a lot together.

New philanthropists have declared their generous intent to add to the resources that are needed, and I welcome the spirit embodied in the commitments they have made. Special regards go to Bill Gates for his generous and enlightened commitment. We welcome them.

GAVI might not have come to life if Jim Wolfensohn had not taken the initiative to get many of us together in the meeting he hosted in March last year. This signalled increased interest in the World Bank in the area of immunizations, and this commitment offers some real hope for positive developments ahead. Carol Bellamy and I have already responded by increasing our own organizational and personal involvement. We have all made explicit reference to the importance of immunization in statements to our Boards or Regional Committees this autumn.

The bilaterals, the developing countries, the technical agencies and the research community are with us. Their role is crucial.

Following the meeting last year the working group, representing some of the major partners around this table, has struggled to put together GAVI. We have navigated through some difficult waters, but now we are out in the open and wind is filling our sails. The course is set. We have moved quickly in recent months in order to translate our intentions into action. This has required informal approaches, including the selection of Board members. As we get more established, we will change to more explicit procedures.

This is the first official meeting of the constituted Board of GAVI. It is therefore appropriate that we start by adopting the recommendations made during the meeting of the so-called "Proto-Board" which convened in Seattle on 12 and 13 July of this year and has set the path for today's meeting.

Once we have done so, I would like to suggest that this assembly will review in some detail the proposal to establish a Global Fund for Children's Vaccines. I propose that, after a short presentation, we discuss the principles and some of the operational aspects of this fund.

This will naturally lead us to dedicate some time to issues relating to vaccine procurement. In such a short meeting, I do not expect that we will come up with final detailed recommendations. Nevertheless, I expect that we can all agree on basic principles and set the directions which the Secretariat and the Working Group can follow in further shaping up the rules that will govern the purchase of vaccines through the Global Fund.

Finally, I propose that we project ourselves into the immediate future and review possible options for an official launch of the Alliance and of the Global Fund early next year. The Secretariat will be presenting to us the plans that they have made and we should give clear directions on how we want to move forward.

Now let us get down to business. Time is in every way not on our side. But we have the commitment to make a real difference. I suggest that we strike an informal tone in our work, and I will invite all to briefly introduce yourselves and the constituency you represent before we move to the agenda.

Thank you.

Annex 2: Basic principles of the Global Fund for Children's Vaccines

Adopted at the First Board Meeting of the
Global Alliance for Vaccines and Immunization
28 October 1999

Executive summary

The establishment of GAVI provides a unique opportunity for the international community to make clear and sustainable strides towards saving millions of children's lives and protecting people's health against vaccine-preventable diseases. Greater equity and timeliness in protecting the children of the poorest countries with vaccines is the most important challenge facing GAVI. One of the new and powerful tools proposed to meet this challenge and develop a renewed global commitment to immunizations is the establishment of the Global Fund for Children's Vaccines.

The Proto-Board for the Global Alliance for Vaccines and Immunization (GAVI) that met in Seattle 12-13 July, 1999 decided on the mission, objectives, functions and structure of the Alliance and established the GAVI secretariat. The basic modalities for the work of the Alliance have been developed, and the Global Fund for Children's Vaccines (hereafter called "The Fund") is being established with an initial grant of $750 million over 5 years from the Bill and Melinda Gates Foundation.

GAVI will build on a comprehensive multi-year immunization plan within the health sector in each country, supported by a National Inter-agency Coordinating Committee, or equivalent. This plan will be used to explore various tools to strengthen the financing of national immunization services including national resources, coordinated support by multilateral and bilateral partners, use of concessional development bank loans, Debt Relief funds, and where appropriate support from the Fund.

The Working Group is hereby proposing the basic principles for the use of the Fund.

It is anticipated that the Fund eventually will have three separate sub-accounts or windows, for:

- procurement of new vaccines,
- access and infrastructure, and
- research and development.

This document presents guidelines for the use of the first window of the Fund, to support initially the procurement of vaccines for Hepatitis B, *Haemophilus influenzae* type B, Yellow Fever and related safe injection equipment.

Countries with small resources and a lack of purchasing power have been considered to be in greatest need of financial support for the new vaccines. It is proposed that this be initially interpreted as those with a GNP/capita equal to or less than 1,000 USD (i.e. "IDA-like") and a population of less than 150 million. Even with these restrictions the cost of the new vaccines will exceed the initial resources of the Fund (Appendix II). In addition GAVI will actively promote immunization for children in all countries through a variety of mechanisms.

Thus the Board adopted the following initial principles for procurement of new vaccines and safe injection equipment.

a) Procurement of vaccines for *Hepatitis B, Haemophilus influenzae* type B (Hib), Yellow fever (routine use), and related safe injection equipment (auto-destruct syringes and safe disposal boxes).

b) Proposals from governments only (except in emergency situations) with the concurrence of a National Inter-agency Coordinating Committee will be considered.

c) Countries' initial eligibility criteria would be those with a GNP/capita equal to or less than 1,000 USD and a population below 150 million.

d) Review criteria will include i) burden-of-disease, ii) adequate delivery system as measured by DTP3 coverage of at least 50%, iii) effective co-ordination mechanism, iv) immunization assessment (EPI, financing, new vaccines), and v) multi-year immunization plan.

e) Time line. The first round of proposals for support from the Fund is planned to take place March-June 2000 with expected first procurements of new vaccines in the latter part of that year. It will be preceded by an intense information and advocacy effort with the aim to inform and prime eligible countries about the opportunities provided by GAVI and the Fund.

1. Introduction: Basic principles of GAVI and The Fund

GAVI and the Fund are designed to renew immunization for the 21st Century, promoting effective immunization services which:

- Reach all children
- Are sustainable;
- Provide the highest level of quality and safety;
- Provide all appropriate existing vaccines and new vaccines as they become available; and
- Allow for the development and use of needed vaccines even if significant industrial country markets do not exist.

GAVI and the Fund recognize that to accomplish the above renewal, improvements need to be made in vaccine delivery infrastructure, the financial tools available to the poorest developing countries, and the resources available for research and development for vaccines primarily of use in developing countries.

GAVI and the Fund seek new ways to strengthen national immunization services and the Partners in Development which support them to work together at national, regional and global levels. GAVI will build on the development of a comprehensive multi-year immunization plan developed by the Ministry of Health in each country, endorsed by a National Inter-agency Coordinating Committee, or equivalent. This plan will be used to explore various tools to strengthen it's immunization services, including national resources, coordinated support by multilateral and bilateral partners, concessional development bank loans, Debt Relief funds and where appropriate support from the Fund.

The Fund, therefore, is only one of a number of financing tools which need to be used in support of a comprehensive and well-coordinated plan. The Fund will be a powerful tool to catalyze the new framework of cooperation in immunization, by providing some of the resources needed to implement the plan.

The Fund will issue The Children's Challenge, a call for all Countries and Partners to synchronize their efforts and increase their total contribution to immunization.

The Bill and Melinda Gates Foundation has responded to this challenge by making the first contribution towards establishing the Fund through a commitment of 750 million USD over five years. The US National Committee for UNICEF has also expressed an interest in providing substantial contributions. As the Fund is fully developed, governments, other foundations, corporations, and major agencies will also be challenged to strengthen their commitment to immunization through multiple channels, including through contributions to the Fund.

2. Purpose

GAVI's most important mission is to promote the right of every child to be protected against vaccine-preventable diseases. The Fund has been set up to assist the poorest countries of the world to achieve this goal. It is anticipated that the Fund will have at least three sub-accounts through which its resources can be utilized to support different aspects of immunization. Different eligibility criteria for each sub-account will be required. The Fund may also, as requested, provide a vehicle for finances dedicated to the guarantee of a future market for a vaccine, creating financial incentives for the development of new vaccines of interest to the developing world (e.g. malaria, HIV, TB). Such mechanisms are currently being explored in close collaboration with GAVI by the World Bank, the Harvard Institute of International Development (Prof. J. Sachs) and the US Government.

3. Use of the Fund

It is proposed that the first sub-account (window) of the Fund be utilized for procurement as follows:

Vaccines

- Hepatitis B
- Haemophilus influenzae *type B (Hib)*
- Yellow Fever (routine use only; not for outbreak control)

Safe Injection equipment

Vaccines purchased through the Fund should always be given using a safe injection. Auto-disable syringes and disposal containers will therefore be provided together with the vaccines purchased through the Fund.

4. Timing and phasing of Fund support

The overall goal of GAVI can only be achieved if the Fund's resources can catalyze sustainable immunization services and be deployed in new countries and for new vaccines over time. Thus it will be essential to develop a phasing out strategy which possibly could be founded on the principles of a revolving fund. The exact mechanisms for doing so remain to be developed on the basis of the experiences from field test countries and first round proposals. Important considerations will be given to financial instruments available at country level including IDA loans, bilateral aid and national resources. A new opportunity which will be actively pursued is the debt relief for Highly Indebted Poor Countries which gives scope for considerable synergies.

5. Country eligibility

Various definitions of country eligibility have been considered. From a macroeconomic point of view it has been considered most appropriate to use criteria analogous to those for IDA credits as general indicators for lack of resources and national purchasing power; GNP/capita. In addition it is proposed to limit eligibility with regard to population size.

Proposed country eligibility criteria:

- Annual GNP/capita equal to or less than 1,000 USD
- Population less than 150 million.

The countries meeting these criteria are shown in Appendix I.

6. GAVI and non-eligible countries

In accordance with its mission GAVI will also work with agencies to promote equitable and timely access to immunizations for children of countries which are not eligible for Fund contributions, including China, India and Indonesia. The latter countries have a GNP per capita of below 1,000 USD, but at the same time considerable production capability for new vaccines, requiring different approaches to insure the availability of current and new vaccines. Buying externally produced vaccines through the Fund is not an effective and sustainable solution for these countries.

Countries which are otherwise eligible but with DTP3 coverage below 50% will also be encouraged to apply for support from the Fund. In these cases GAVI's partners will consider additional support in order to strengthen their immunization services. A system with performance indicators for increased coverage that will be linked to the release of resources from the Fund will also be considered.

7. Review criteria

The explicit criteria to be utilized in the review of proposals will be based upon the experience gained during the testing of assessment tools and modelling of the country coordinating mechansims. Some of the basic principles are:

Burden of disease

The basis for decisions on which vaccines should be purchased for which countries should be based on available data regarding the burden of vaccine-preventable diseases. As new data become available the eligibility of countries in different regions to apply for funds for specific vaccines may change. In principle vaccines may be purchased for any eligible country in which a significant disease burden is established regardless of the region. For the time being and in lieu of data from a specific country, vaccines may be purchased as follows:

- Hepatitis B: Globally
- Hib: Africa; Latin America; Middle East; countries in other regions if supported by epidemiological data
- Yellow fever: Africa and Latin America according to regional recommendations.

Capacity

An essential element of the review will be the capacity of the health system to deliver the requested vaccines effectively. Although not a perfect indicator, DTP3 coverage has been considered to be the most straightforward and feasible approach for measuring capacity in this respect.

The proposed minimum criterion is national DTP3 coverage above 50% according to WHO/UNICEF reporting. The assessed quality of the reporting as well as trends in coverage may also be considered in the overall judgement of health systems capacity.

National commitment & planning

The process of preparing a proposal to the Fund and particularly the roles of the government and partner agencies are expected to vary from country to country. In order to reduce the workload of developing new proposals available information should be used to the greatest extent possible. However, information on certain core activities will be required in each country to allow a satisfactory review:

- Immunization Services Assessment (EPI, Financing, New Vaccine Introduction): The partner agencies are now developing standardized tools for these national assessments which will be made available for use by all agencies. GAVI will encourage a coordinated use of these tools in order to decrease the overall of burden placed on countries by various agencies. Many countries have already undertaken regular reviews and should have the required information readily available. The new tools may become especially important in monitoring and evaluation (see below).
- Country Coordinating Mechanism: In many eligible countries there are already mechanisms for co-ordination of immunization activities, typically in the form of National Inter-Agency Coordinating Committees, chaired by the respective government. These mechanisms should build upon and be linked to other health sector coordination activities. In countries which rely on external support for immunization activities the functions of the coordinating committees and the role of the partners are crucial. It may be necessary to introduce in-depth assessments of the effectiveness of the coordinating function and to request the cooperating partners to make special efforts in this area.
- Multi-Year Immunization Sector Plan: An essential role of the coordinating mechanism will be to assist in the development of a long-term plan if not already existing. This plan should include general health sector information including national health accounts as well as technical and financial elements of the immunization services. The financial commitments should include that of the government, partner agencies, utilization of concessional loans as appropriate, and other financing mechanisms. In particular a credible system for meeting the costs of the traditional six EPI vaccines is required. Resources to cover a financing gap for the purchase of the new vaccines may then be requested from the Fund. As further sub-accounts of the Fund are developed, resources for infrastructure may also become available for countries that are not fully capable of meeting these needs.

8. Proposed structure and process

The proposed structure and main functions of the Fund appear in Annex III. The main procedures are outlined below.

Priming of countries

In order to make possible an early start of the activities financed by the Fund plans are being made to initiate a substantial advocacy and support effort in the countries concerned. The main partners will have the responsibility to carry this out at the country level supported by the advocacy task force and the GAVI Secretariat. These activities are planned to include the dissemination of information materials, workshops and seminars as well as specific technical support when required.

It is hoped that this effort will strengthen countries' resolve to intensify their immunization efforts and clarify the support that can be provided by GAVI, its partners and the Fund.

Field testing

In parallel with these efforts a few countries will be selected in order to develop the instruments mentioned above and assure simple and effective procedures. This work is planned to result in more specific guidelines and procedures to be applied in the first round by March-June 2000.

Funding procedures

Governments of eligible countries may make formal proposals for funding to the GAVI Secretariat, based upon these guidelines. The proposals will be screened for completeness by the GAVI Secretariat before being reviewed by the Working Group, strengthened by the necessary expertise. The Working Group will present proposals and recommendations to the GAVI Board for decision. Based upon the GAVI Board's authorization, funds can be released from the Working Capital Account to procure vaccines through UNICEF or other mechanisms as appropriate.

GAVI will control disbursements from the Working Capital Account. This account will be held at and managed by UNICEF on behalf of GAVI. Contributions may also be made directly to the Working Capital Account. When required to meet the needs of approved country proposals, the GAVI Board will make a request to the Fund for replenishment of the Working Capital Account.

The function of the Fund Board will be complementary to that of the GAVI Board in order to avoid duplication of effort. The Fund will have a small secreatariat composed of a Director with experience and responsibility regarding fundraising and a part-time accountant. The Fund will be incorporated as a charity, with a small, independent board (5-6 members), chosen by GAVI, including expertise in public health, finance and advocacy as well as representatives of major contributors.

The Board of the Fund will have the responsibility for overseeing the ongoing management and investment of the Fund's resources. It is anticipated that the Fund will fulfil its mission through the use of the Working Capital Account. However, if this mechanism should turn out not to be effective, the Fund may consider other solutions.

Agreement procedures

These are not yet fully developed. However, it is anticipated that after approval of support from the GCVF an agreement will be negotiated between the concerned country and one or several of GAVI's implementing agencies. It may be supplemented by a letter of understanding signed by the main external partners and the government to ensure that all requirements for a successful implementation of an expanded immunization program will be in place.

9. Monitoring and evaluation

It is essential to develop an effective system for monitoring and evaluation. This will be done for each country through the national coordinating mechanism. A full evaluation will be planned to take place 1-3 years after the initial disbursement of funds. Through appropriate planning, every effort will be made to co-ordinate this evaluation with other reviews within the health sector. Based upon the country experiences the Working Group will provide a set of recommendations to the Board at a future meeting.

10. Challenges and issues

A successful utilization of the Fund will require that GAVI addresses multiple challenges at the global, regional, and country levels. Some of the more significant challenges include:

- Securing country ownership and commitment;
- Establishing indicators of country commitment to immunizations (financial and otherwise);
- Phasing in and phasing out Fund resources while working towards sustainability;
- Safeguarding the Fund's resources in order to ensure commitments to the poorest countries;
- Ensuring that the Fund supplements or catalyzes an increase in resources available for immunization in countries as opposed to replacing current sources. Increased country and partner contributions, concessional loans, and conditionalities in connection with debt relief for the Highly Indebted Poor Countries are among the options for increasing available resources;
- Ensuring government responsibility and at the same time setting specific requirements for effectiveness of coordination.

11. Timeline

Starting Nov., 1999	Initial priming of countries by advocacy & support through country level representatives Field testing of proposal tools
January, 2000	Davos Launch; First formal materials to countries
March, 2000	Proposals received from “Field Test” countries Guidelines and call for proposals to all eligible countries
Mid-May, 2000	Deadline for submission of proposals
Late-May, 2000	Working Group review of proposals
June, 2000	GAVI Board decision on recommendations of the Working Group, request for funding to the Fund. Fund to transfer resources to the Working Capital Account at UNICEF.

Appendix I to Annex 2:

Birth cohorts and DTP3 coverage in GFCV eligible countries

Country	GNP/ capita (USD) 1998	Birth cohort (thousand) 1997	DTP3 coverage (percent) 1997	DTP3 coverage (percent) 1998	Comments
Somalia	n.a.	469	-	**24**	
Myanmar	n.a.	939	90	87	
Liberia	n.a.	109	-	**19**	
Bhutan	n.a.	74	87	86	
Afghanistan	n.a.	1076	45	**34**	-
Djibouti	n.a.	22	62	-	
Bosnia & Herzegov	n.a.	37	79	89	
Turkmenistan	n.a.	122	98	99	
Ethiopia	100	2606	63	57	
Congo, Dem Rep	110	2228	18	**18**	
Sierra Leone	140	208	26	56	+
Burundi	140	270	-	50	
Guinea-Bissau	160	47	63	-	
Niger	190	479	28	**25**	
Malawi	200	486	95	96	
Eritrea	200	141	60	60	
Tanzania	210	1295	74	74	
Nepal	210	775	78	76	
Mozambique	210	803	61	77	+
Chad	230	313	24	**23**	
Rwanda	230	274	77	-	
Burkina Faso	240	508	70	-	
Mali	250	492	52	53	
Madagascar	260	598	61	68	
São Thomé	280	6	73	73	
Cambodia	280	365	70	64	
Sudan	290	922	79	72	
Yemen	300	785	57	68	
Central Afr Rep	300	129	-	**45**	
Nigeria	300	4056	45	**21**	-
Uganda	320	1026	58	**46**	-

Country	GNP/ capita (USD) 1998	Birth cohort (thousand) 1997	DTP3 coverage (percent) 1997	DTP3 coverage (percent) 1998	Comments
Zambia	330	366	70	-	
Vietnam	330	1729	95	94	
Togo	330	179	33	**36**	
Lao PDR	330	200	60	55	
Kenya	330	981	36	64	+
Gambia	340	48	96	96	
Angola	340	570	41	**36**	
Tajikistan	350	190	95	94	
Bangladesh	350	3403	98	78	-
Kyrgyz Republic	350	118	98	97	
Comoros	370	23	48	75	+
Benin	380	234	78	81	
Nicaragua	390	170	94	86	
Ghana	390	700	60	68	
Mongolia	400	58	92	94	
Mauretania	410	100	28	-	
Haiti	410	250	35	**22**	-
Moldova	410	58	97	97	
Pakistan	480	5263	74	79	
Armenia	480	46	87	82	
Azerbaijan	490	128	-	97	
Senegal	530	353	65	65	
Guinea	540	305	53	56	
Lesotho	570	71	57	-	
Cameroon	610	550	44	**48**	
Zimbabwe	610	354	78	70	
Congo, Rep	690	119	23	-	
Côte d'Ivoire	700	525	70	64	
Honduras	730	202	93	96	
Solomon Islands	750	14	72	69	
Guyana	770	18	88	90	
Sri Lanka	810	326	97	94	
Albania	810	65	99	96	
Uzbekistan	870	654	96	99	
Papua New Guinea	890	144	45	58	+
Georgia	930	71	92	86	
Bolivia	1000	260	78	76	
Total of 68 countries		40505			
13 countries below 50% DTP3 coverage		11434			
55 countries with above 50% DTP3 coverage		29071			

Countries with GNP/cap below 1,000 USD and population above 150 million

Country	GNP/ capita (USD) 1998	Birth cohort (thousand) 1997	DTP3 coverage (percent) 1997	DTP3 coverage (percent) 1998	Comments
China	750	20410	96	98	
India	430	24871	90	73	-
Indonesia	680	4688	90	65	-

Countries close to GNP/cap of 1,000 USD and/or with uncertain data:

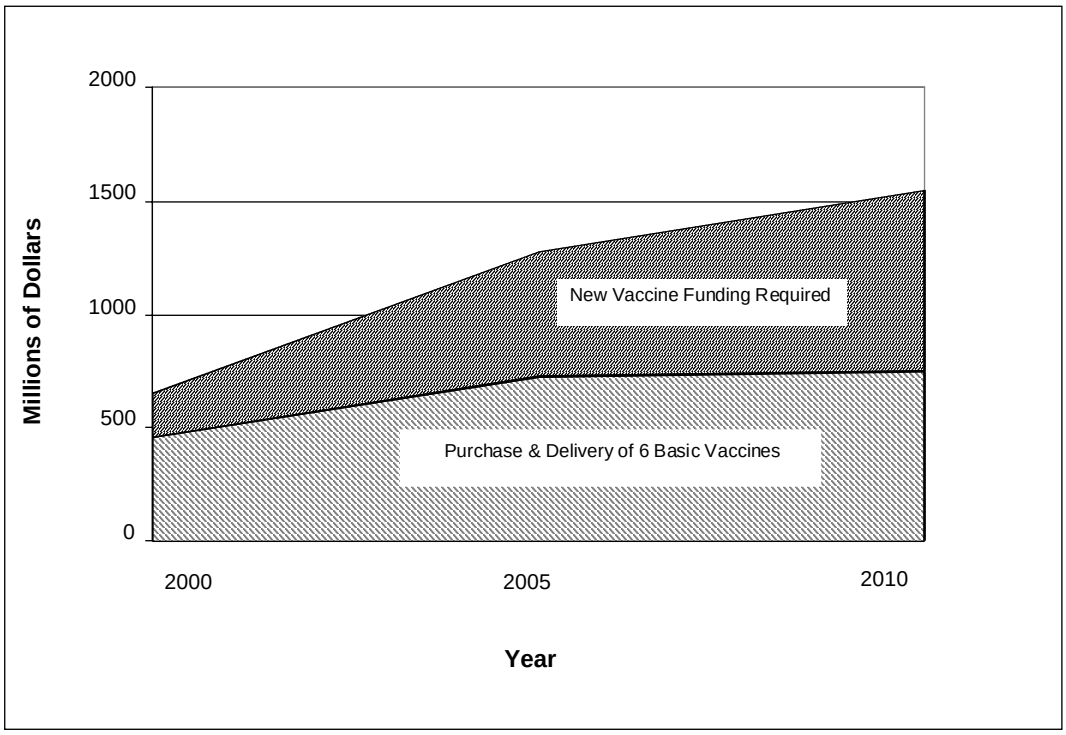
Country	GNP/ capita (USD) 1998	Birth cohort (thousand) 1997	DTP3 coverage (percent) 1997	DTP3 coverage (percent) 1998	Comments
Cuba	n.a. / 1170	146	98	99	
Korea, DPR	970 ?	491	-	37	
Ukraine	850 – 1200	496	-	98	

Sources:
- GNP/cap: World Bank as of June 30, 1999
- Birth cohorts: UNICEF The Progress of Nations 1999 (based on UN Population Div 1998 World Population Projections)
- DTP3 coverage: EPI Global Summary for 1998 (in print)

Comments:
- \+ marks those with > 10% increase in DTP3 coverage 97-98
- \- marks those with > 10% decrease in DTP3 coverage 97-98

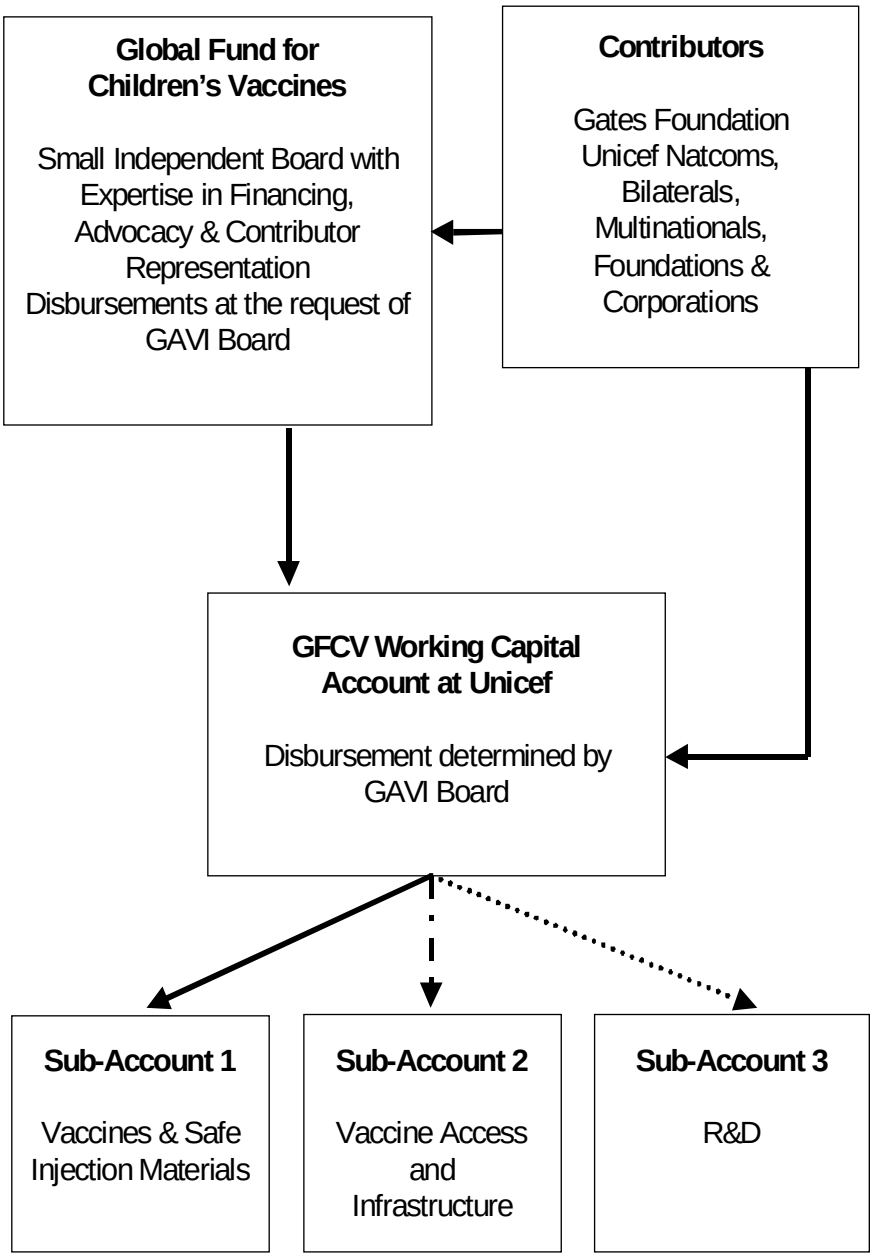
Appendix II to Annex 2:

Figure: Funds Necessary for Vaccines in the Poorest Countries, 2000-2010



Appendix III to Annex 2:

Figure: Structure - Global Fund for Children's Vaccines



Annex 3.1: Basic principles of GAVI and the Fund

Overhead presentation by Dr Mark Kane at the
First Board Meeting of the
Global Alliance for Vaccines and Immunization
28 October 1999

1) Basic principles of GAVI and The Fund

GAVI and The Fund are designed to renew immunization for the 21st Century, insuring that all children have access to effective immunization services which:

- Are sustainable
- Reach all children
- Provide highest levels of quality and safety
- Provide all appropriate existing vaccines and new vaccines as they become available
- Allow for the development and use of needed vaccines even if significant industrial country markets do not exist

GAVI and The Fund recognize that to accomplish the above renewal, improvements need to be made in:

- vaccine delivery infrastructure,
- the financial tools available to the poorest developing countries, and
- the resources available for research and development for vaccines primarily of use in developing countries.

GAVI and The Fund propose a new way for National Immunization Services and the Partners in Development which support them to work together at national, regional and global levels.

The Global Fund for Children's Vaccines is being established with an initial gift of $750 million over 5 years from the Bill and Melinda Gates Foundation.

It is anticipated that The Fund eventually will have three separate sub-accounts or windows, for:

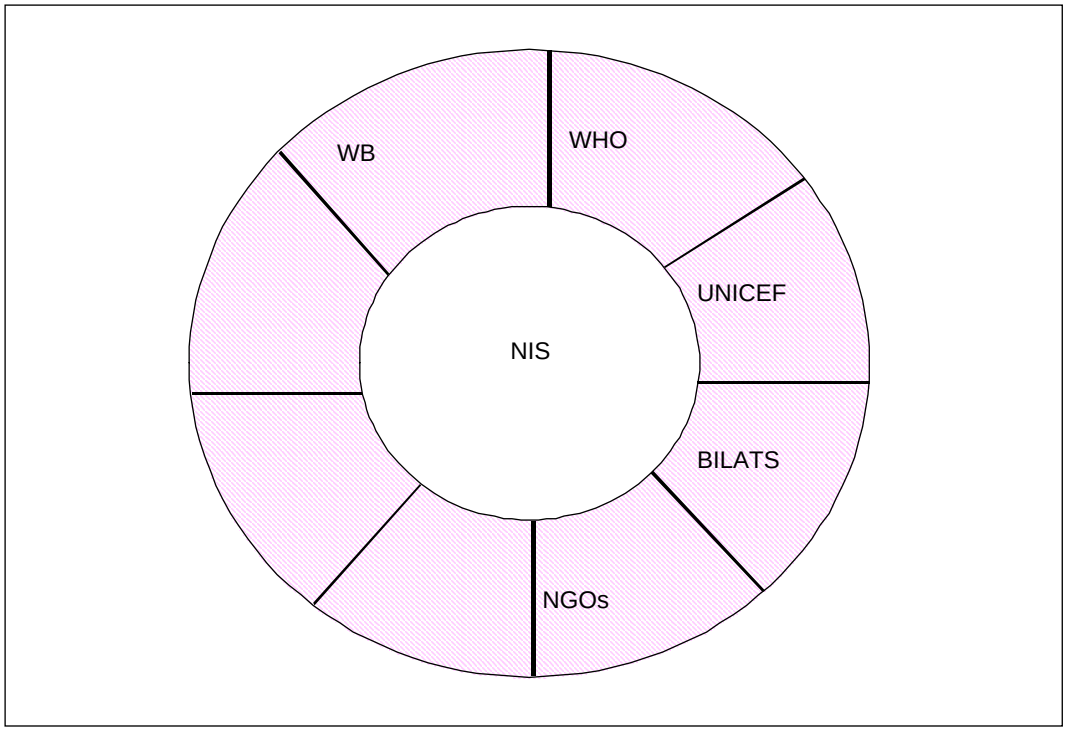
- procurement of new vaccines,
- access and infrastructure, and
- research and development.

The first window of The Fund will support the procurement of vaccines for Hepatitis B, *Haemophilus influenzae* type B, Yellow Fever and related safe delivery equipment.

The Fund should never be understood in isolation. It is one financial tool in a comprehensive package of assessment, planning, and coordinated partner support.

2) National Interagency Coordinating Committee (NICE)

Figure A: National immunization service (NIS)



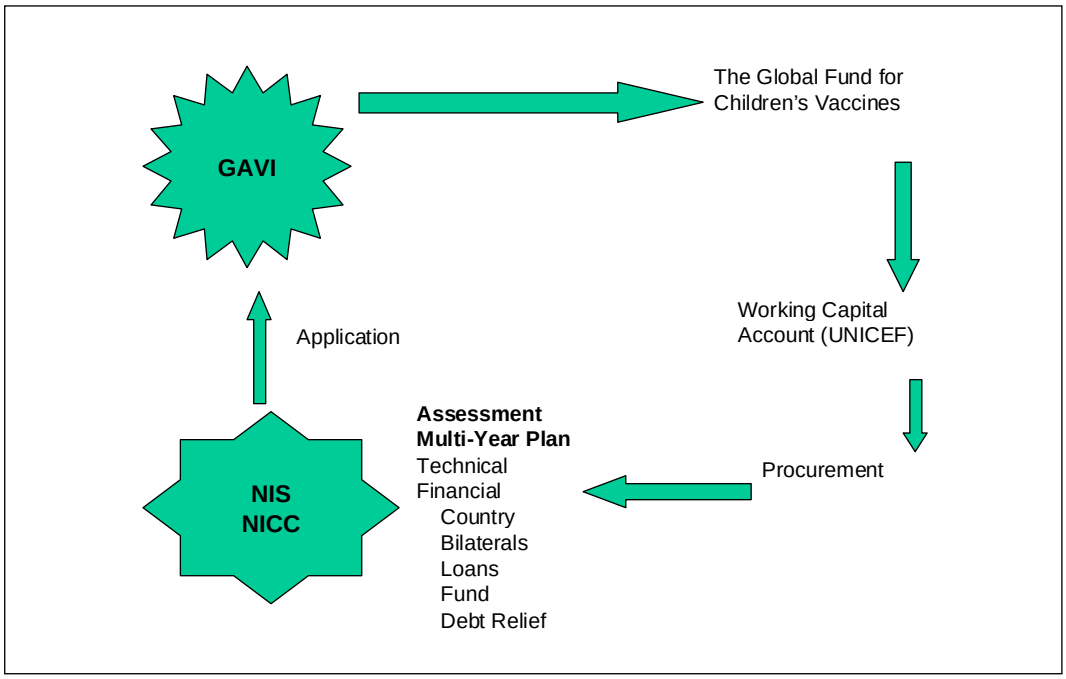
Partner support to NIS:

- coordinated (National ICC=NICE)
- reflects agreed upon common goals
- provides “real” technical and financing solutions
- each agency does its job

Assessment plan:

- Technical
- Financial
  - Country
  - Bilaterals
  - Loans
  - CV Fund
  - Debt relief

Figure B: Operation of the new vaccines window



3) The Working Group proposes that the Board

- Endorses the concept, proposed structure, and operations of the Global Fund for Children's Vaccines
- Adopts the following guidelines for the use of sub-account (window) number 1,"Procurement of new vaccines and safe injection equipment":
  - Hepatitis B globally
  - *Haemophilus influenzae* type B (Hib) where appropriate
  - Yellow fever (routine use)
  - related safe injection equipment (auto-destruct syringes and safe disposal boxes).

4) Global Fund for Children's Vaccines

Proposals only from governments (except in emergency situations):

Initial country eligibility criteria

- GNP/capita equal to or less than 1,000 USD
- Population less than 150 million
  - excludes from Window 1 India, Indonesia, China
  - make their own vaccines
  - inappropriate for Fund to purchase vaccines

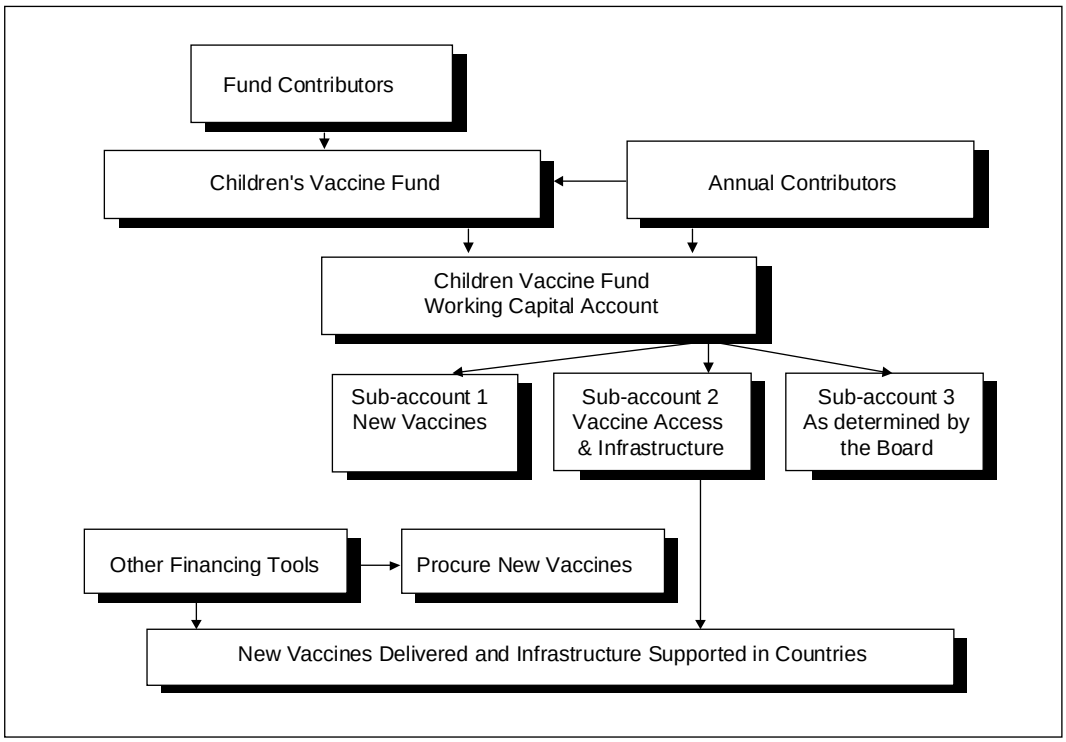
Review criteria:

- burden-of-disease
- adequate delivery system as measured by DPT3 coverage of at least 50%
- effective co-ordination mechanism
- immunization assessment (EPI, financing, new vaccines)
- multi-year immunization plan
- monitoring and evaluation

Table A: Timeline

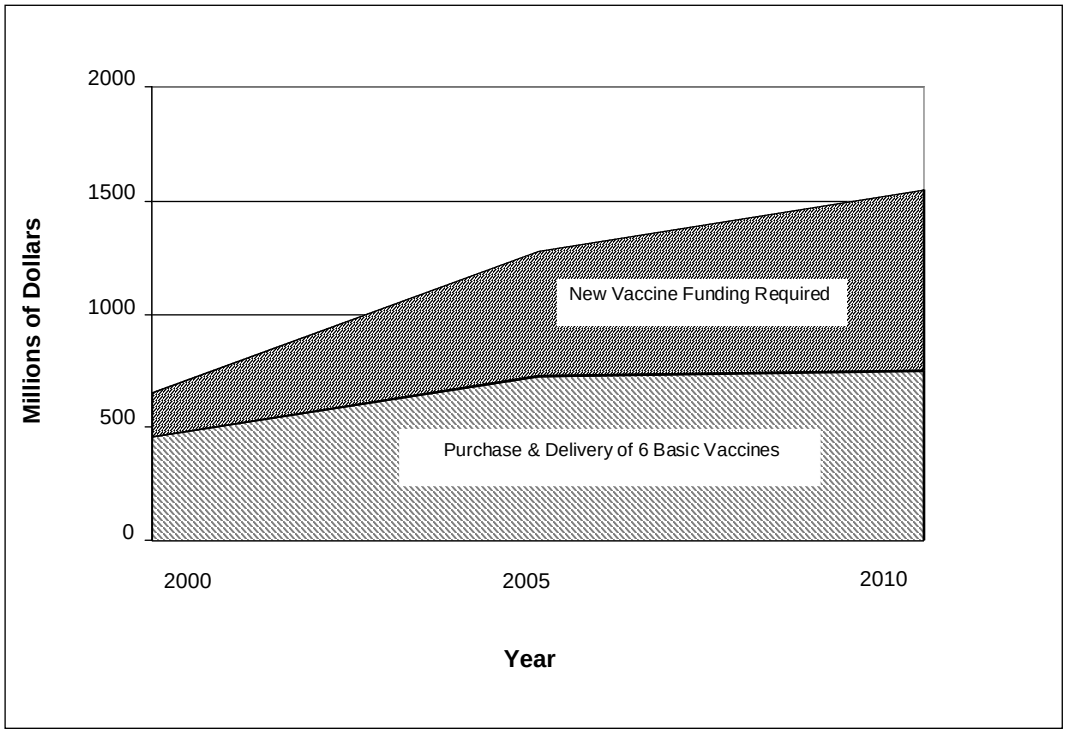
Starting November, 1999	• Initial priming of countries by advocacy & support through country level representatives • Field testing of proposal tools
January, 2000	• Davos Launch; First formal materials to countries
March, 2000	• Proposals received from "Field Test" countries • Guidelines and call for proposals to all eligible countries
Mid-May, 2000	• Deadline for submission of proposals
Late-May, 2000	• Working Group review of proposals
June, 2000	• GAVI Board decision on recommendations of the Working Group, request for funding to the Fund. • Fund to transfer resources to the Working Capital Account at UNICEF.

Figure C: Global Fund for Children's Vaccines



- The Fund will have a separate, small, independent, international Board, chosen by GAVI, of public health experts, financial experts, and major contributors
- The Fund will be a charity with tax exempt status in the US (need to match 30%), but will be an international entity
- The Board release funds on the recommendation of the GAVI Board
- The Fund will have a small secretariat composed of a Director and a part time accountant
- The Fund will choose an investment firm
- The Fund will work with the US Committee for UNICEF for US fundraising, and possibly other National Committees for UNICEF and other international entities
- The Children's Challenge

Figure D: Funds Necessary for Vaccines in the Poorest Countries, 2000-2010



5) Recommendations of the GAVI Working Group

Table B: All Eligible Countries According to Available Data

Total Birth Cohort	37,108,000
Annual Doses of Hep B Vaccine Needed When Fully Integrated*	106,932,000
Annual Cost of Hep B & Syringes ($0.75/dose)	$80,199,000
Annual Doses of Yellow Fever Vaccine Needed**	15,463,000
Annual Cost of Yellow Fever and Syringes ($0.30/dose)	$4,638,900
Annual Doses of Hib Needed***	74,232,000
Annual Cost of Hib & Syringes ($2.50/dose)	$185,580,000

* Includes only countries not using Hepatitis B vaccine
** Primarily African countries; some Latin American countries may also be eligible
*** Includes only African and Latin American countries not using Hib vaccine

Annex 3.2: Global Alliance, Board Discussion Paper: Public sector vaccine procurement approaches

Prepared by Mr. Piers Whitehead, Vice President,
Mercer Management Consulting, London
for the First Board Meeting of the
Global Alliance for Vaccines and Immunization
28 October 1999

Introduction

This paper has been prepared at the request of Dr. Tore Godal, General Secretary of the Global Alliance for Vaccines and Immunisation. It is based on a series of professional assignments undertaken by the author in the vaccine field for UNICEF, the CVI, the World Bank and several private sector organisations, as well as conversations with, and documents[1] provided by, Dr Godal.

Objectives and Executive Summary

The purpose of this paper is to assist GAVI in making the optimum decision, given its charter and goals, as to future vaccine procurement policy. We believe that GAVI has a significant opportunity to enhance access to newer vaccines for children in the poorest countries. In our view, realising this access rests, inter alia, on two procurement factors: shifting to a contractual (versus tender) approach; and investing in the organisation and skills necessary to operate a contractual approach successfully. A summary of our reasoning is laid out below:

1. There is a critical link between procurement policy and the achievement of programmatic goals.
2. There are tensions within GAVI's objectives, in essence requiring trade-offs between achieving the lowest possible prices today and maximising private sector investment to serve the developing countries in the future.
3. The development and commercialisation of new vaccines is dominated by a small number of Western companies with pharmaceutical parents.
4. GAVI's objectives require that these companies invest in R&D for specific, largely developing country, diseases, provide adequate capacity early to meet global demand, at the most affordable price possible.

1. GAVI Financing Task Force Working Papers, September 1999; GAVI Report of the proto-board meeting, 12-13 July 1999; The PAHO Revolving Fund, Paper by Phyllis Freeman, JD, 9 March 1999; Vaccine Procurement mechanisms: WHO position, draft 24 January 1999-09-29.

5. Pharmaceutical company R&D is funded from current sales revenue and directed at markets perceived to be commercially attractive.

6. Capacity has historically been limited to the commercially attractive markets when a new vaccine is introduced, although GAVI is in a strong negotiating position to change this paradigm.

7. Pricing is largely determined by product lifecycle maturity and production economics, which enable marginal pricing. The extreme price tiering exhibited by the EPI vaccines is available only when a product is mature.

8. Current tender-based procurement approaches exploit these factors to achieve very low prices, within a simple and transparent process. However, they fail to provide any incentive for companies to invest in developing country products or supply.

9. Current mechanisms also do not discriminate between different levels of need in the developing world, which may disadvantage the position of the poorest nations.

10. Therefore, if GAVI wishes to support a broad set of objectives, its procurement policy must manage the product lifecycle and try to discriminate between developing countries on the basis of need.

11. The generic components of such a policy would include longer-term contractual commitments together with a recognition that access earlier in the lifecycle will require higher prices than those achieved for the existing EPI vaccines.

12. Underlying this generic policy, there are a range of options for the degree and mechanism by which GAVI targets its procurement policy to balance the tensions in its objectives.

13. Such a policy has the potential to transform the paradigm of vaccine supply to the developing world, but faces both political and organisational implementation challenges.

The importance of procurement policy

In considering what vaccine procurement policy to adopt, GAVI should recognise that the implications of the decision go beyond the obvious ones of price, volume and procedures. Procurement policy should be seen as a major tool by which GAVI can seek to influence third parties in support of its objectives. The obvious third parties are the governments and health authorities of developing countries, and the developers and manufacturers of vaccines.

Governments and health authorities may receive an economic benefit from a procurement policy, through lower prices for vaccines than would be the case if they purchased them independently. In return for this benefit, GAVI may be able to have a positive influence on the development of in-country immunisation programmes. PAHO cites this as a significant benefit resulting from its approach to, and management of, the Revolving Fund[2].

2. Paper by Phyllis Freeman, as above.

For the private sector developers and manufacturers of vaccines, the procurement policy of GAVI and other international agencies has a substantial impact on the commercial opportunity which the developing world represents. In particular, the commitment of international agencies to adding an antigen to a programme, or increasing coverage, can substantially increase the size of the market, measured in terms of volume. In addition, international agencies represent a low cost route to developing country markets for producers, as compared to country or regional marketing organisations.

On the other hand, procurement approaches which target and achieve very low prices reduce the value of this extra volume to the producers. In some cases, where lower priced tender-procured demand substitutes for higher priced country demand, the effect might be to reduce the overall value of the market, although volume would remain constant. On its own, this should not be a concern to the public sector: it is not responsible for the levels of profitability of its suppliers. Given, however, that supplier behaviour is primarily driven by economic profit, it would become a concern if it threatened the ability of the public sector to rely on private sector suppliers to meet its goals.

Procurement policy is therefore a powerful tool to influence both countries and suppliers. However, the source of influence over countries - low prices - reduces influence over suppliers. A rational decision about the best way to balance this conflict can only be taken if there is clarity around the objectives being sought.

GAVI's objectives

GAVI has the following strategic objectives[3]:

1. Improving access to sustainable immunisation services.
2. Expanding the use of all existing safe and cost-effective vaccines.
3. Accelerating the development and introduction of new vaccines.
4. Accelerating research and development efforts for vaccines and related products specifically needed by developing countries.
5. Making immunisation coverage a centrepiece in the design and assessment of international development efforts.

It is not the purpose of this paper to discuss all the programmatic or political challenges encompassed by this set of objectives. From the perspectives of procurement policy and the private sector, however, it is important to recognise the tensions in what is being sought.

3. Report of the Proto-board meeting, as above Annex 3.3: Global Alliance, Board Discussion Papers.

To the extent that available funds are a constraint on sustainability or expanded use, the public sector should design a procurement policy which minimises the prices paid for vaccines. Such a policy will, however, reduce the profitability and commercial attractiveness of developing country vaccine markets, especially if it is pursued in a manner which does not distinguish between creating new demand and substituting for existing, higher priced demand. In this context, it is unlikely that private sector developers and manufacturers will make the necessary investments in both R&D and production capacity, either to make new vaccines available earlier to developing countries, or to develop vaccines specifically targeted at developing country needs.

In considering the criteria for a procurement policy for GAVI, we are now confronted by two sets of trade-offs. There is a trade-off between country leverage (low prices) and company leverage (higher prices). There is also a trade-off in dealing with suppliers between wanting the lowest possible prices today, and the maximum possible investment for the future.

Vaccine company economics

Introduction

GAVI requires two things from commercial suppliers to meet its objectives: new product development, and product access. New product development is a function of the targeting and scale of R&D resources devoted by the private sector to GAVI's priority disease targets. Access is a function both of available production capacity and pricing. GAVI's success in meeting its objectives will be a function of understanding and managing its economic levers over the suppliers via its procurement policy.

The extent to which GAVI should be sensitive to encouraging private sector development investment via its procurement policy depends on two factors. First, the relative importance attached to introducing new vaccines to developing countries, as opposed to, for example, expanding the use of existing vaccines or strengthening country immunisation systems. We are not qualified to comment on this question. Second, acceptance of the premise that meaningful quantities of any new vaccine of interest to GAVI is almost certainly going to come from a small number of large private sector Western vaccine producers, until the product matures.

In the recommendations Mercer made to UNICEF in December 1993, the relative weight attached to achieving access to new vaccines and the changes underway in the industry and environment contributed heavily to our conclusion that UNICEF should move to a more partnership-based procurement approach. In arriving at this conclusion, we took into account three factors:

- The evidence that the vaccine industry was entering into a period of significant product innovation, driven in part by advances in biotechnology and in part by a virtuous circle, whereby the commercial success of new products stimulated further investment in new products.
- The fact that ownership of the major vaccine producers was consolidating, under predominantly pharmaceutical parent companies (SmithKline Beecham, Merck, Pasteur-Merieux/Connaught/Aventis, Lederle/Praxis/Wyeth/AHP, Behringwerke/Sclavo/Chiron).

- The observation that commercial control (as opposed to scientific discovery) of recent products resided, and for new products would likely continue to reside, predominantly in these companies. Examples include recombinant Hepatitis B, Hepatitis A, HIB, Varicella and Rotavirus.

We saw no reason to be concerned about declining competition in the traditional EPI vaccines, and indeed recognised that new developing country entrants would likely result in lower prices still for traditional EPI vaccines under tender procurement approaches.

These three trends listed above mean that if the public sector is to achieve access to new products and influence investment for the future, it is on these companies that it should focus its efforts. To enable a better understanding of what this might mean in practice, we discuss below three factors: the pharmaceutical business model, which determines where the companies direct their R&D effort, with what expectation of return; capital expenditure decision making, which determines how much capacity is available when; and production economics, which explains when and why companies are willing to supply at low prices in return for significant volumes.

Factors influencing company R&D spending

The pharmaceutical business model rests firmly on two pillars. One is innovation, funded by substantial research and development expenditure. The second is patent protection for the products resulting from this innovation process, allowing the company to charge high prices for the product for a limited period. In biologicals, it is often the case that process know-how, whether patented or not, can also represent a substantial barrier to imitators. The gross margin (proportion of sales revenues represented by product manufacturing costs) for a successful pharmaceutical company is typically around 80%. In other words, the selling price is five times the cost of manufacture.

The most successful pharmaceutical companies typically focus most of their R&D programmes on a limited number of targets and therapeutic areas. This decision reflects both the very high costs of an R&D programme, and the costs and dangers of fragmentation of trials, launch and marketing efforts. One industry rule of thumb is that a target has to have forecast sales of $250m per annum, at attractive gross margins, to be considered for development by a major pharmaceutical group.

Once a drug loses patent protection, prices typically fall sharply as generic manufacturers start production. After a transition period, the pharmaceutical company will often stop marketing the compound in question. Although the comparison is not perhaps perfect, the basic EPI vaccines are largely generic products.

Pharmaceutical companies fund their R&D programmes out of the revenues arising from sales of current products. This has two implications. First, activities or divisions which have high margins will tend to receive more R&D funds, less attractive activities less. Second, the companies will tend to serve the needs of consumers who provide them with an attractive market today: the affluent consumer will find the companies more attentive to his or her future health needs than the poor consumer. Some analysts believe that the US market is setting much of the R&D agenda for pharmaceutical companies, notwithstanding differing European priorities, driven by the higher profits available from pharmaceuticals in the US.

From this overview, we conclude that the major pharmaceutical/vaccine companies will invest in R&D in disease targets of especial developing country interest when they see a commercially attractive market in place in such countries. Promises that the future will be different from current experience are of limited value. In 1998 we conducted a study for the World Bank, to examine "pull" (market guarantee) mechanisms to encourage R&D into an HIV vaccine. Most major companies questioned the credibility of such a mechanism, given the lack of a commercially attractive market for their products today.

We would further conclude that, if GAVI does place a high priority on new product development efforts, it is necessary to focus on a very narrow number of targets, given the scale of resources involved.

Factors influencing available capacity

Typically, once a product is in late-stage development, a vaccine company will take the decision to invest in production capacity. Having such capacity in place is often a factor in receiving marketing approval. This decision is significant in both size (tens of millions of dollars) and in terms of risk: oversize the facility and the company wastes large sums of money; undersize the facility, and the company cedes attractive market share to a competitor.

There are two aspects of this decision which should concern GAVI. First, the costs of constructing and operating a vaccine manufacturing plant are highly scale-sensitive. In essence, this means that the capital and operating cost per unit of capacity falls as facilities get larger. Whilst the relationship varies by vaccine, process and plant configuration, the slope of these curves is generally around 65-70%: the cost per unit of capacity for a plant with double the capacity of another will be 65%-70% lower, all other things being equal.

In the interests of clarity, it is worth making a few supplementary points around this scale sensitivity. First, in absolute terms, a larger plant is more expensive to build and operate than a smaller one. Second, given the distribution of the birth cohort, the capital expenditure required to serve the global market is a multiple of that required to serve, say, OECD markets. Third, once the capacity is in place, it only delivers economic benefit to the company if it is actually utilised: otherwise, it will be higher cost, in both unit and absolute terms, than a smaller, better utilised, facility.

The second aspect of potential concern to GAVI is the relative immutability of capacity decisions, once taken. The requirements of good manufacturing practice as they affect biologicals mean that capacity expansion is both very expensive and time-consuming. Once a plant is built which is inadequate to serve global demand, GAVI will usually have to rely for access on new entrant capacity, perhaps limited during the period of patent protection, or on capacity creep, discussed below.

We believe that GAVI has substantial potential negotiating power with suppliers to gain early access to newly introduced vaccines, if its procurement mechanism is so designed. Through an early commitment to purchase – before the plant has been constructed – GAVI could substantially reduce the risk of the capital expenditure for the company. It would also increase the operating and capital efficiency of the plant once built, by enabling the construction of a larger plant than would otherwise have been the case, with some proportion of its utilisation underwritten. From the company's perspective, this factor is likely to extend the period when it faces limited or no competition.

Such a model, which might be called "planned access", would also require significant commitments from GAVI. These would obviously be subject to commercial negotiation at the time, but we would expect to see four elements, as follows:

1. The price of the vaccine would have to justify, or substantially justify, the incremental investment and operating costs incurred in providing the capacity GAVI contracts for.
2. The commitment would need to be multi-year, where the number of years involved might be greater than five.
3. GAVI would need to enter into a contractual, enforceable, purchase agreement.
4. GAVI would almost certainly be restricted as to which markets it was permitted to supply vaccine to, or procure on behalf of. In particular, GAVI should expect to be restricted to markets where there is little or no prospect of a commercial market emerging. This restriction may, however, work to GAVI's advantage, in that it will make more manageable the financial commitment required to satisfy point 1 above.

In return for such commitments, we expect that GAVI would be able to achieve early access in significant volumes to newly introduced vaccines at prices substantially below those prevailing in OECD markets. We understand that such an offer was made at the time of SmithKline Beecham sizing its Recombinant Hepatitis B facility, but not acted upon by the public sector.

Factors influencing pricing

Introduction

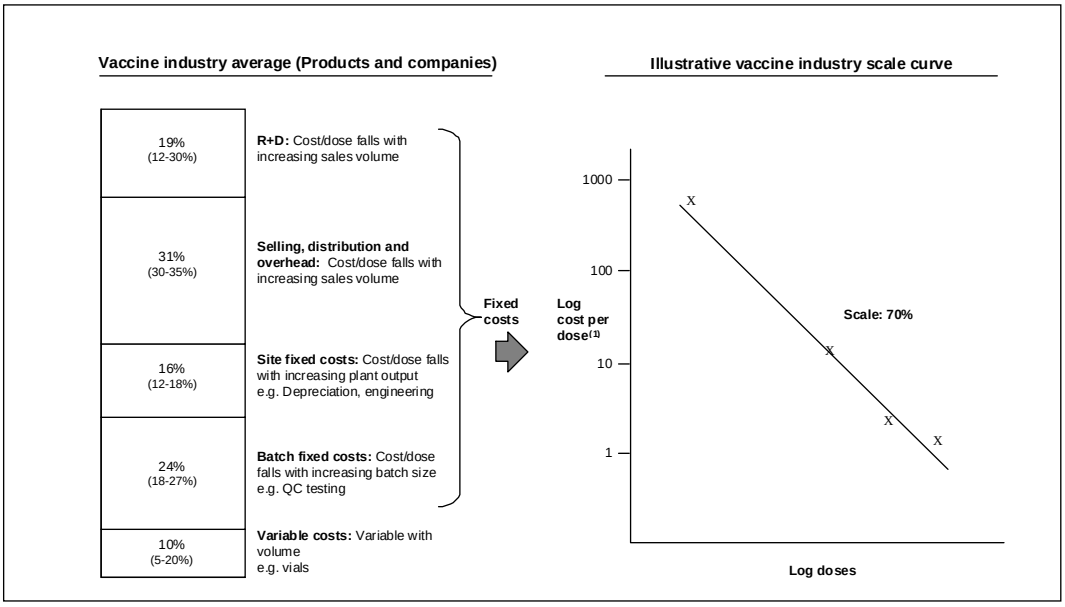
The pricing of current EPI vaccines is characterised by heavy tiering. The prices paid by the international public sector are a fraction – often a very small fraction – of those in OECD markets. There are other markets which exhibit price tiering: for example, the passenger air travel business. The author is, however, unaware of any other market which exhibits it to the same extent.

In our view, the major drivers of price tiering in the vaccine market are manufacturing economics and product lifecycles. A critical precondition for tiering is the relative difficulty of parallel imports in biologicals, since manufacturers would be unlikely to supply at very low prices if doing so threatened higher priced markets. The international public sector is also relatively cheap to deal with, both because of centralised purchasing and typically large vial presentations. This effect, however, would only explain a difference of cents per dose, whereas the prevailing differential is usually dollars per dose.

Fixed costs allow marginal pricing

The key to understanding vaccine manufacturing economics is the insight that the vast majority of costs are fixed. A cost is considered fixed when its total value does not vary with volume: cost per unit therefore falls in line with volume increases. The opposite of a fixed cost is a variable cost, the total value of which fluctuates in line with volume: variable cost per unit is a constant. Exhibit 1 illustrates this distinction.

Exhibit 1: The vaccine industry cost structure is predominantly fixed: Cost falls as more doses are produced



Note (1): Vaccines involving significant royalty payments have effectively higher variable costs, and are therefore less scale sensitive

We estimated in our 1993 UNICEF study that variable costs, costs which are constant per unit regardless of volume produced, represented only 3% of the average EPI vaccine cost structure. Whilst this figure might vary somewhat from vaccine to vaccine, the key point is that variable costs are of very limited economic importance. For EPI vaccines, these costs would be the vial, any sterile diluent, and growth media. Newer vaccines may have higher variable costs because of royalty payments to holders of intellectual property rights.

The rest of the cost structure is fixed, either at the batch, department/site or corporate level. This means that cost per unit will fall in a linear fashion until capacity limits (maximum batch size, maximum department or site throughput) are reached. It therefore makes economic sense for a manufacturer with spare capacity to sell vaccine so long as the price is higher than variable costs, and so long as the volume thus gained is not substituting for higher priced volume. This phenomenon is known as marginal pricing, whereby a product is sold for less than its full cost because it makes an incremental contribution to fixed costs. The manufacturer's profits will, in effect, be higher by the surplus over variable cost achieved, even though, if costs were allocated proportionately across the volume sold, the volume sold at low prices would show a loss.

It is not, however, correct to deduce from this that a purchaser buying higher volumes will always achieve lower prices. The lowest price achievable is the fully marginal price, which only covers variable costs. Large volumes of a given vaccine will probably require dedicated bulk and filling lots, and the price will therefore have to cover the additional manufacturing and quality control costs for a manufacturer to be willing to undertake supply. Supply in large volumes may also require capital expenditure to remove bottlenecks in the production process. The price on offer will have to be sufficient to offer the manufacturer a prospect of a return on this investment.

This point is supported by the data collected for our 1993 study for UNICEF, which showed that international government tenders for relatively small volumes of vaccine achieved the lowest prices. Since then, the volumes purchased by the international public sector have risen, and prices have fallen. However, the year to year relationship between price and volume is not reliable, and at least some of the price decline is probably attributable to shifts in the mix of suppliers.

Product lifecycle leads to overcapacity

Manufacturing economics, and in particular, the fixed cost nature of the business, is one driver of price tiering. It enables manufacturers to offer low prices on some volume whilst still realising an economic benefit. The second driver is the product lifecycle, and in particular, the over-capacity it gives rise to. The existence of excess capacity at multiple producers creates the economic and competitive conditions which make manufacturers willing to offer the lower tiers of prices.

As we see it, the product lifecycle has three distinct phases: new product launch, market penetration, and product maturity. These phases are summarised in Exhibit 2.

Exhibit 2: Product lifecycle impact

Historically, price development both within and across markets has been heavily influenced by product lifecycle.

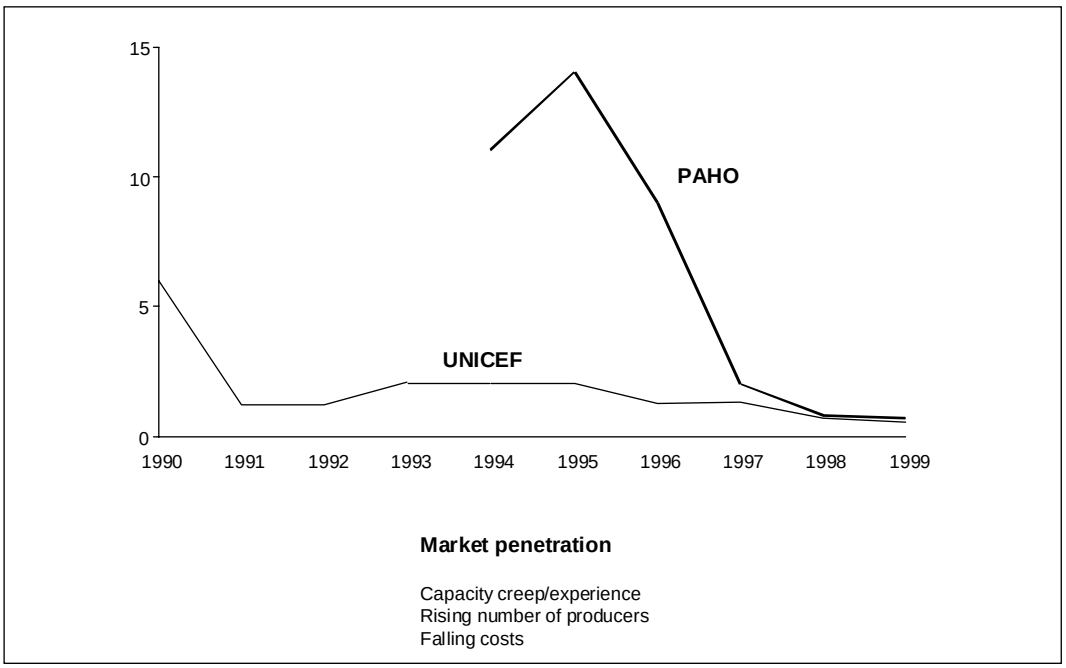
Factor	New Product Launch	→	Market penetration	→	Product maturity
Number of producers	Low (1)		Multiple, industrial		High: Mixed industrial/developing
Pricing	High, uniform		Tiered within and across markets (industrial/private): high average		Tiered within and across markets (global): low average
Cost	High		Medium		Low
Profitability	High		High		Moderate
Available capacity	Low		High		Potential surplus
Availability	Poor		Good in industrial		Good globally
Market demand	Low		High, industrial and private		High, global
Examples:	Rotavirus, DTaP, Hepatitis A		HIB, Hepatitis B		DTP, BCG

On launch, there is typically a single producer, owning product and process intellectual property. This period of exclusivity often lasts for only one or two years, given that the basic science which enables vaccine development is largely conducted in the public sector. The capacity put in place by this producer will probably be quite limited, representing a trade-off between demand estimates and the risk of incurring unnecessary capital expenditure. Capacity estimates in biologicals would in any case appear to be a somewhat inexact science. Given, however, both the low prices and uncertain funding which currently characterise developing country vaccine markets, capacity planning is unlikely to take full account of global demand.

From the manufacturer's perspective, the launch phase is characterised by high prices and high costs: high prices to capitalise on the period of exclusivity; high costs both because volumes are low and manufacture is thus scale-inefficient, and because vaccine production costs are sensitive to experience effects. As a manufacturer gains experience in making a particular vaccine, certain process measures will improve, and in particular bulk batch yields. As a result, even without additional plants or capital expenditure, capacity tends to rise over time.

The second phase, market penetration, is likely to see further manufacturers enter the field, either through their own development efforts or through licensing of the original manufacturer's intellectual property. Capacity increases sharply, both as a result of new competitors and the experience-based capacity creep referred to above. Some price tiering is now evident, in particular to encourage uptake in the more price sensitive developed markets. However, capacity is still ultimately calibrated to developed country demand, and the over-capacity is insufficient to require manufacturers to offer large volumes at very low prices for developing countries.

Exhibit 3: Prices fall rapidly as product matures.
Example: Hepatitis B



In the third phase, product maturity, the number of manufacturers rises as intellectual property protection expires. This, coupled with continued capacity creep, results in significant over-capacity, which in turn creates the conditions necessary to enable extreme price tiering, and global availability of the vaccine. Exhibit 3 illustrates how this lifecycle effect works, using Recombinant Hepatitis B as an example.

In summary, the price tiering that exists for EPI vaccines today is a product of fortuity and time: fortuity that the economics of manufacture allow it, and parallel import concerns are manageable; and time as the creator of over-capacity. We would conclude that, early in a product's lifecycle, the negotiating power of any purchaser, regardless of volume, is much weaker than late in the lifecycle. This is not to say that volume is without value, simply that its value, relative to investment risk and price, is lower. A procurement policy which seeks to accelerate access to newer products needs to take account of these factors.

Current tender procurement approaches

Successes and failures

The current procurement approaches used by international public sector bodies are to launch a single tender for all countries requiring vaccine on an annual or biennial basis. Subject to minimum quality standards and volume availability, the sole selection criterion is price. This approach has delivered significant successes for international public health, and offers other benefits to the public sector. It would be wrong to underestimate the positive aspects of this procurement approach, but it is equally misleading not to recognise its shortcomings, which are significant.

The most important success of this approach is the contribution it has made to make possible generally high levels of coverage of the EPI vaccines in the developing world, including the world's poorest nations. Whilst recognising that pricing is only one barrier to access to immunisation, it is in our view uncontroversial to state that the low price points established by this procurement mechanism have been critical to this achievement. The leverage accruing to the international public sector as a result of its procurement activities will also have contributed to country-specific programme improvements.

The clarity and simplicity of the selection criteria used provide two other important side-benefits to the public sector. First, the approach is cheap to operate, and requires limited technical, commercial or negotiating expertise. Second, judgement plays very little role in the process: assessed against the single criterion of price, the public sector can be confident it has got the best available deal, and the process is relatively immune to improper influence of any kind.

This very simplicity, and in particular the reliance on a single criterion, price, also explains the major failings of this procurement approach. In particular, the public sector has to date failed to add vaccines to the programme on a global basis. Such vaccines exist, and there is a clear public health need. At least in part, this failure can, we think, be attributed to procurement policy. The prices paid for current EPI vaccines are achievable precisely because little or no investment has been made explicitly to serve developing country markets. Such investment is, however, required for newer, often patented, products. The existing market and procurement policy do not support the case for such investment.

The current procurement policy has a second subtle, but nonetheless real, effect on company behaviour. Buying vaccines as if they were a commodity, on a transparent open tender basis, is alien to the pharmaceutical business model. This inevitably leads to adversarial relationships between public and private sectors. It is hard to measure or define exactly what impact this has. It would be naïve, however, to believe that the companies, understanding the product lifecycle and its implications for profitability, do not try to manage it to their advantage.

Broader issues with tender procurement

There are two critical assumptions which underlie a procurement policy of uniform tender procurement for all developing countries. The first is that higher volumes will always result in lower prices. The second is that achieving the lowest possible price for all developing countries is necessarily a public health good.

The first assumption is extremely questionable, as discussed above, Factors influencing pricing. Lowest prices are available to purchasers of relatively modest volume, which can be considered fully marginal. By grouping together a large number of developing countries, the current mechanisms ensure that the price must cover at a minimum batch and filling lot fixed costs, as well as variable costs. This outcome would be acceptable if the importance of a low price to access was uniform across developing countries, but it is not. The countries served by current bulk procurement systems represent a very wide range of levels of economic wealth. In effect, the neediest countries pay more for vaccine today in order that more prosperous countries can pay slightly less. It is this which has led some public health thinkers to advocate tenders differentiated by countries' economic position.

We also believe it is dangerous to accept unquestioningly the premise that reducing prices, and showing "savings" is always in the developing country public health interest. In our view, it is one of the flaws of the tender procurement approaches in place today that this assumption is embedded in the approach, whereas in fact the measure of success is immunisation outcomes: therefore price matters only when it is the determining factor in achieving the desired outcomes.

We have already discussed at length the fact that current mechanisms provide little or no incentive to vaccine companies to invest in the future of developing country immunisation. We believe that the ramifications of this extend beyond vaccines, into pharmaceuticals more generally.

We also believe that a procurement approach which treats all developing countries alike results in an uneven distribution of benefits from a public health perspective. We can divide the developing world, simplistically, into countries which could afford to buy vaccines for themselves, and countries which cannot. A uniform approach delivers savings to those which could be self-sufficient, at the expense of vaccine company profitability. These savings can be redirected to healthcare or other government expenditure. Indeed, they can be used to purchase vaccines on the world market which are not yet subject to successful bulk procurement. The relatively prosperous country is therefore in a position to overcome the barriers to timely supply of new vaccines that bulk procurement creates. It is the poorest countries, entirely or almost entirely reliant on the international public sector, which pay the penalty.

For both practical and ethical reasons, we conclude that the international public sector should distinguish between countries in its procurement policies based on need.

Options for GAVI

We believe that GAVI cannot use the current procurement mechanisms and expect to meet its objectives. A new approach is therefore needed, and it will in our view need to be segmented along two dimensions: lifecycle stage of the vaccine, and countries to be covered. Along each of these dimensions there are a variety of sub-options to be considered, as well as the question of the relationship between GAVI and existing procurement mechanisms. First, we will define the lifecycle approaches, and their relationship with country coverage issues. Then we will discuss the high-level choices GAVI needs to make.

Issues discussion by vaccine lifecycle stage

1. Mature products: DPT, polio, measles, TT, BCG. These vaccines are already widely available at low prices. We see little benefit to GAVI in seeking to change the method by which they are procured, given that prices are already very low and any absolute saving would be small, and their importance to developed country vaccine manufacturers is small and declining. The pricing of these products may however affect the extent to which commercial vaccine R&D is undertaken in developing countries.
2. Maturing products: e.g. Hepatitis B, HIB. Significant capacity exists for these vaccines, but prices are still much higher than for mature products. GAVI's main procurement issue is how to accelerate the introduction of these vaccines. Lower prices will result from targeting the poorest countries, both because of the scale of capacity commitment involved, and because of the reduced risk of cannibalisation of higher priced markets. Lower prices would probably also follow a multi-year commitment.
3. New products: e.g. Rotavirus. Vaccines where significant capacity may not yet be in place. GAVI's issue is how to accelerate access by ensuring capacity is put in place early for developing country needs. The issues here are discussed above, Factors influencing available capacity.
4. Desired products: e.g. HIV, malaria and TB. GAVI's procurement policy will influence company R&D into these three, predominantly developing country, diseases if it takes account of the need to support the development of a commercially attractive vaccine market in the developing world. This might involve acts of commission, such as paying higher prices for existing products, based on company R&D commitments, or acts of omission, such as not supplying where an existing commercial market would be jeopardised.

Options description

GAVI's procurement policy should be determined by the components of the lifecycle where it can have the greatest impact, maturing and new vaccines. This implies some generic components in our view, as follows: multi-year contractual purchasing, a limited number of suppliers, higher prices than those for mature products. Under this umbrella, we see the following options:

1. Targeting procurement on only the most needy countries. GAVI would explicitly limit its activities only to countries meeting a transparent definition of need. Developing countries excluded from this arrangement could continue to seek supply from other procurement agencies, or make bilateral deals. This option would probably yield the lowest prices for GAVI.

2. Broad procurement with a uniform price point. GAVI would seek to procure vaccines for all countries classed as developing who wished it, at a single price point. Since this option virtually guarantees that no commercial market will emerge in the developing world, GAVI should expect some resistance from companies. Further, it implies a much larger capacity commitment. These two factors are likely to result in higher prices or slower availability, or both, than option 1.

3. Broad procurement with a transparent tiered price point. As for option 2, but countries or donors would pay different prices based on the relative economic position of the country concerned. This will be more attractive to companies if it results in a higher average price than option 2. However, we would expect it to cause political difficulties with the countries being asked to pay the higher prices, and some of them might choose to procure independently.

4. Broad procurement with an obscured tiered price point. As for option 3, but with a single headline price, which would be adjusted to reflect the differing levels of country need. The mechanisms for such an adjustment are various: if the uniform price point were high, it might take the form of companies donating vaccine pro-rata to supply to the poorest countries, to bring down the effective average price; or make contributions to a fund for R&D aimed at the poorest country markets. If the price were low, one can envisage lump sum payments to companies meeting supply targets, to raise the effective average price. The latter is less likely to run into objections from more prosperous developing countries, but is perhaps harder to administer and design.

We see two factors as determining which of these options GAVI will want to pursue. One is the political acceptability of targeting or tiering based on need. The other is the extent of resources at GAVI's disposal, which may dictate procurement scope.

Implementation issues and conclusions

A new paradigm of vaccine supply to the developing world is urgently required and GAVI, through its procurement policy, is well positioned to make it possible. Whichever option is ultimately selected, the approach is likely to represent significant implementation challenges. In particular, the understanding and skill of GAVI's negotiators will have to be of a much higher level than that required to run current procurement approaches.

It will also be important to recognise that there is going to be a risk that GAVI enter into contracts that, at some point during the life of the agreement, and with the benefit of hindsight, may appear over-generous to the private sector. Assuming that GAVI negotiated the best possible deal at the outset, this will represent a challenge to the leadership and political will of GAVI. The answer to such critics should be that GAVI is about achieving programmatic outcomes with a high degree of certainty, and this is not compatible with always getting the lowest possible price.

Annex 3.3: Public sector vaccine procurement approaches

Overhead presentation by Mr Piers Whitehead at the First Board Meeting of the Global Alliance for Vaccines and Immunization 28 October 1999

1) What difference can GAVI make?

A procurement perspective

- Additional funds
- Supply of additional vaccines to developing countries
  - Primarily proprietary products

Figure A: The procurement challenge: Managing product lifecycle

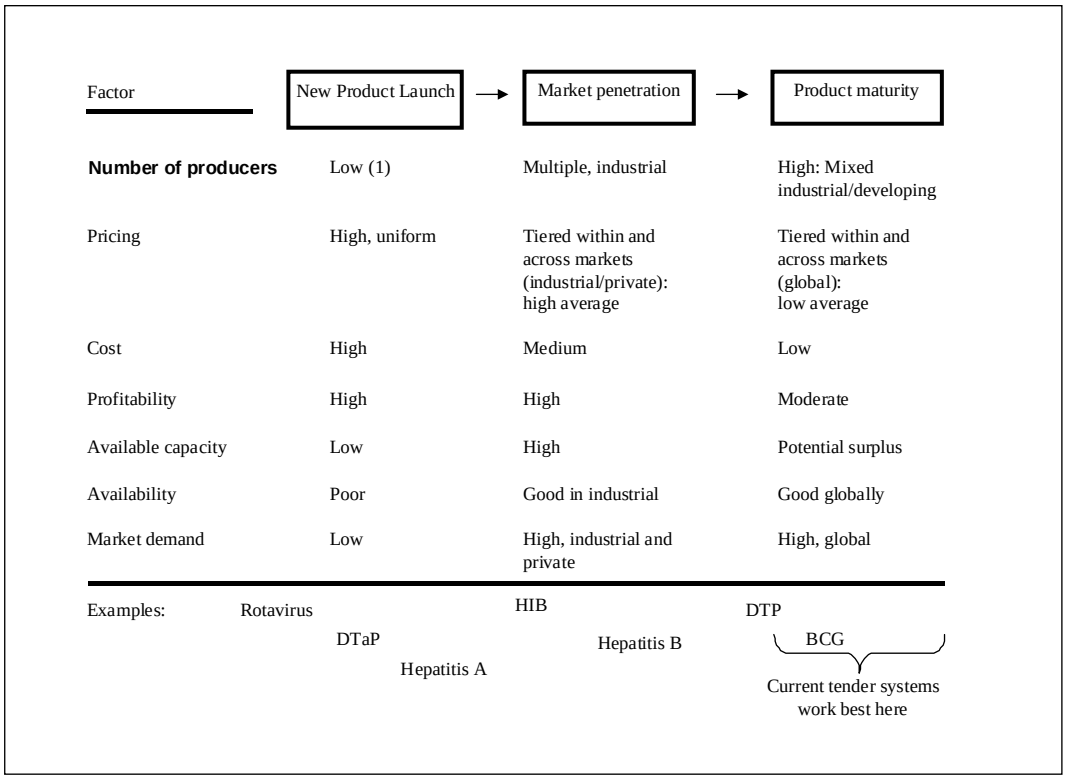
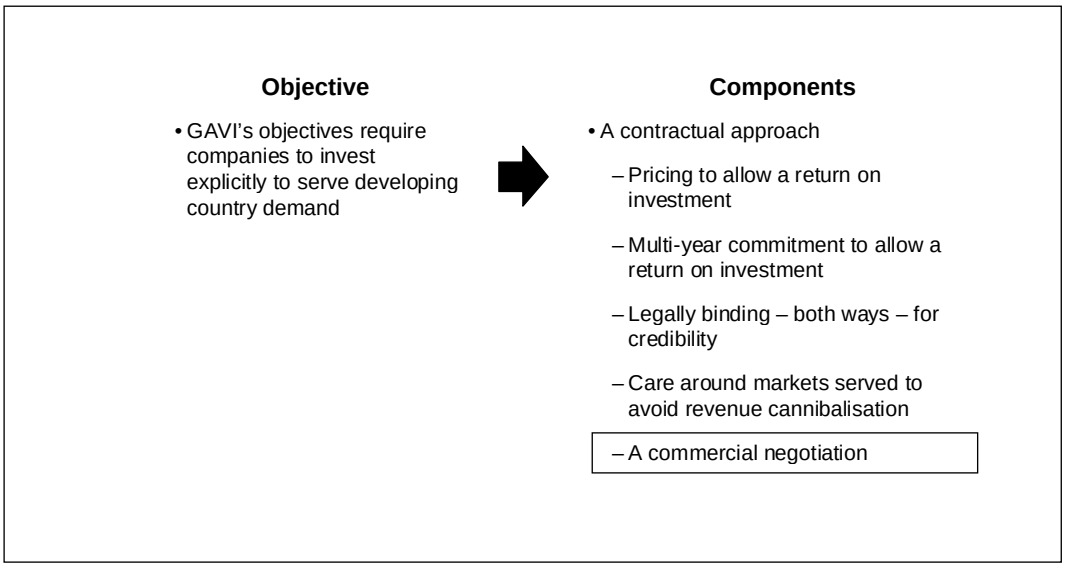
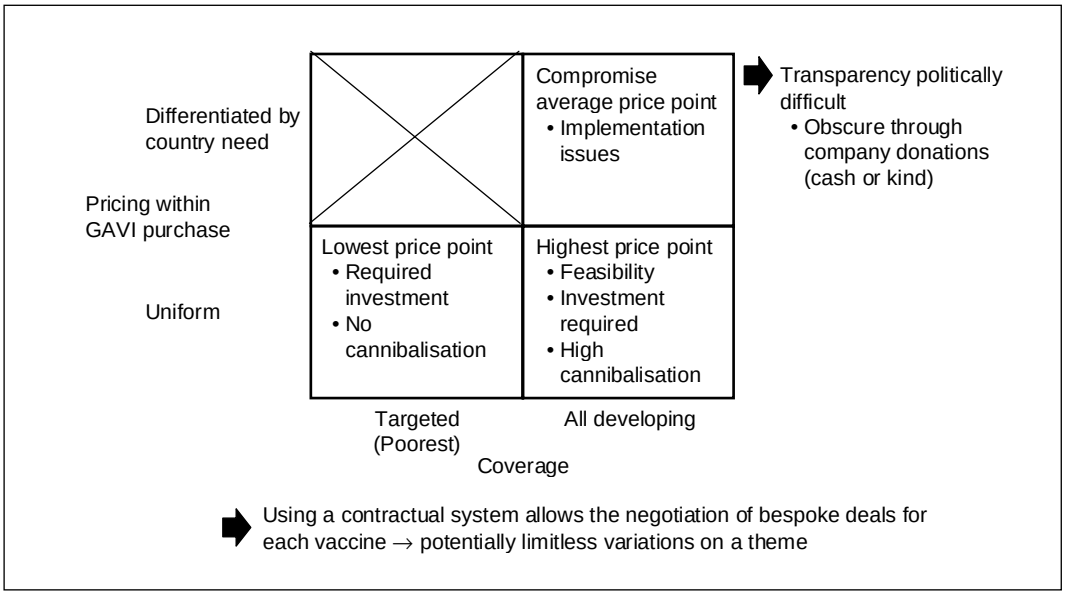


Figure B: Components of early access



2) Options within a contractual approach

Figure C: Two key dimensions: Coverage and pricing



3) Key success factors

- Procurement skill
  - Much more complex than tender system
  - Requires investment, training, new skills, commercial nous
- Clarity around objectives
  - Public health outcomes, not
  - e.g. Vaccine industry structure
  - e.g. Company profitability
- Leadership/political will
  - 20/20 hindsight
  - Outcome focus
  - Learning
- Building in sustainability

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- Dr. Steven Landry, Technical Advisor, USAID **
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- Mr. David Alnwick, Chief, Health Section
- Dr. Suomi Sakai, Senior Health Advisor, Immunization, Health Section **

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- Dr. Michael Sholtz, Executive Director, HTB*
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