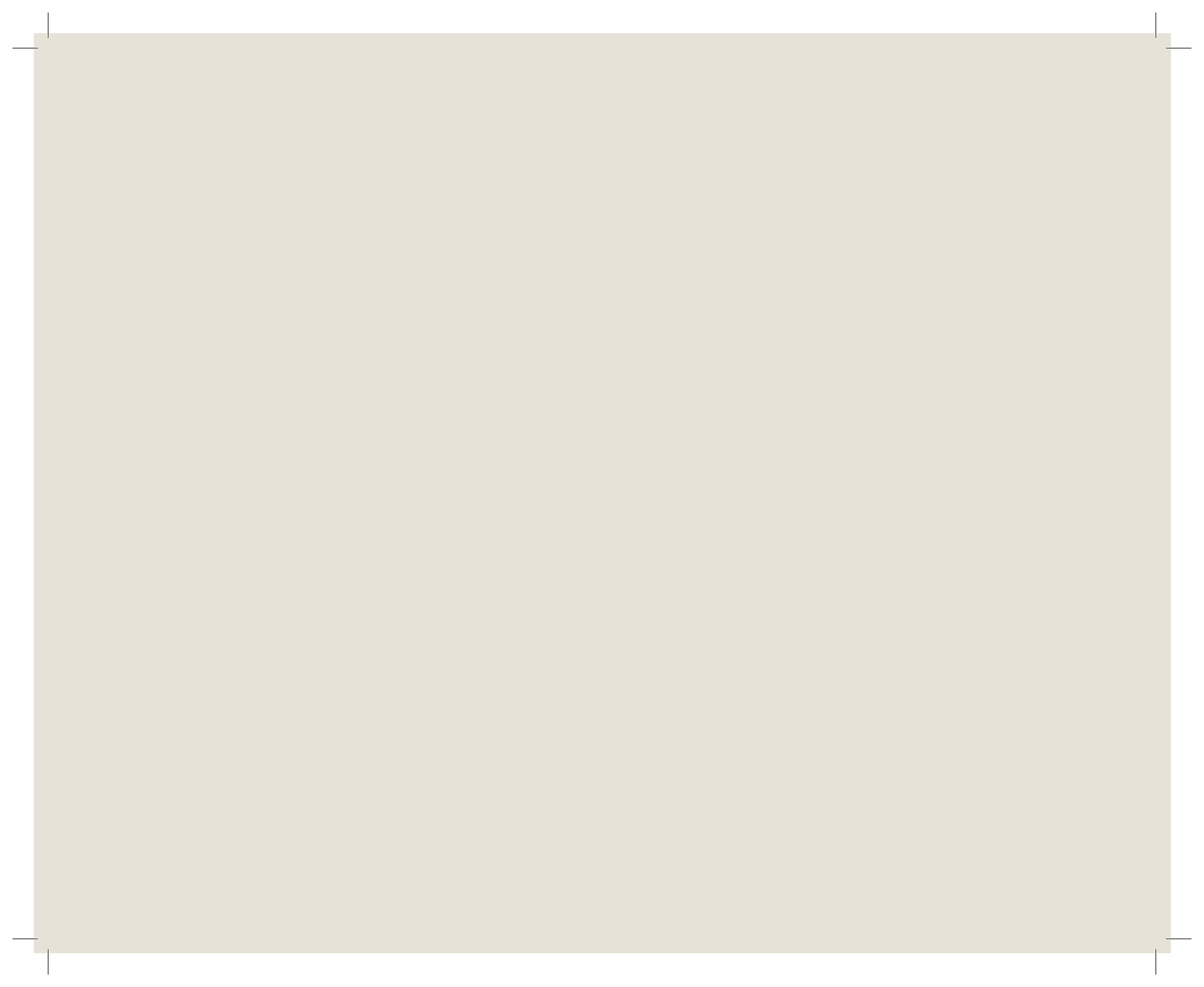


GAVI Alliance Handbook

Country proposal
and monitoring processes





**GAVI Alliance
Handbook**

Country proposal
and monitoring processes

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CONTENT

- 1 What is GAVI ? 7**
 - 1.1 The GAVI Alliance 7
 - 1.2 The GAVI Fund 9
 - 1.3 The International Finance Facility for Immunisation 9
 - 1.4 The GAVI proposal and monitoring process 11

- 2 Who are the actors ? 15**
 - 2.1 Country governments 15
 - 2.2 Interagency coordination committees 15
 - 2.3 Health sector coordination committees 16
 - 2.4 GAVI regional working groups 17
 - 2.5 GAVI Alliance Secretariat 19
 - 2.6 GAVI Independent Review Committee 20
 - 2.7 GAVI Boards 21
 - 2.7.1 GAVI Alliance Board 21
 - 2.7.2 GAVI Fund Board 23
 - 2.7.3 GAVI Working Group 23

- 3 What types of support does GAVI offer? 27**
 - 3.1 Immunisation services support 29
 - 3.1.1 What does the GAVI Alliance provide? 29
 - 3.1.2 What are the conditions for immunisation services support? 31
 - 3.1.3 How long does immunisation services support last? 31
 - 3.2 New and underused vaccines support 32
 - 3.2.1 What does the GAVI Alliance provide? 32
 - 3.2.2 What are the conditions for support? 34
 - 3.2.3 Co-financing new and underused vaccines 35
 - 3.2.4 Prioritisation of vaccine products supplied by GAVI 38
 - 3.2.5 How long does new vaccine support last? 39
 - 3.3 Injection safety support 39
 - 3.3.1 What does the GAVI Alliance provide? 39
 - 3.3.2 What are the conditions for injection safety support? 40
 - 3.3.3 How long does injection safety support last? 40
 - 3.4 Health system strengthening support 40
 - 3.4.1 What does the GAVI Alliance provide? 41
 - 3.4.2 What are the conditions for HSS support? 42
 - 3.4.3 How long does HSS support last? 42
 - 3.5 Civil society organisation support 43
 - 3.5.1 What does the GAVI Alliance provide? 45
 - 3.5.2 What are the conditions for CSO support? 45
 - 3.5.3 How long does CSO support last? 47

4 How to apply for GAVI support? 49

- 4.1 Proposal development 51
- 4.1.1 HSS proposal development 52
- 4.2 Proposal submission 53

5 How does GAVI provide support? 55

- 5.1 Direct funding transfers 56
- 5.2 Vaccine and injection material 56
- 5.3 Cash in lieu of supplies 58

6 What are GAVI's monitoring and evaluation requirements? 61

- 6.1 Annual progress reporting 63
 - 6.1.1 Objectives 63
 - 6.1.2 Preparation and submission 64
 - 6.1.3 Outcome 65
- 6.2 Data quality audit 67
 - 6.2.1 Objectives 66
 - 6.2.2 Methodology 66
 - 6.2.3 Outcome 67
- 6.3 Vaccine management assessment 68

Annexes

Annex 1

Documents required with proposals 71

Annex 2

Calculating ISS investment and reward payments 73

Annex 3

List of URLs 75

Annex 4

Contact information 78

Acronyms

AD	autodisable
APR	annual progress report
BCG vaccine	Bacille Calmette Guerin vaccine (against tuberculosis)
cMYP	comprehensive multi-year plan
CSO	civil society organisation
DQA	data quality audit
DQS	data quality self-assessment
DTP vaccine	diphtheria, tetanus and pertussis vaccine
GIVS	Global Immunization Vision and Strategy
GNI	Gross National Income
HSCC	health sector coordination committee
HSS	GAVI health system strengthening support
ICC	interagency coordination committee
IRC	Independent Review Committee
INS	GAVI injection safety support
ISS	GAVI immunisation services support
JRF	WHO-UNICEF Joint Reporting Form
NVS	GAVI new and underused vaccine support
OECD-DAC	Organisation for Economic Cooperation and Development-Development Assistance Committee
RWG	regional working group
SWAp	sector-wide approach
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
WHO	World Health Organization



1 What is GAVI?

The GAVI Alliance is a global health partnership representing stakeholders in immunisation from both private and public sectors, working together to achieve a goal no single agency or group could achieve on its own. The Alliance makes possible accelerated access to existing underused vaccines, strengthened health and immunisation systems in countries, and the introduction of innovative new immunisation technologies, including new vaccines. This prevents millions of deaths worldwide and contributes to the achievement of the Millennium Development Goal for child health – a two thirds reduction in the number of deaths in the under-fives by 2015.

This Handbook is intended to assist countries and their partners in navigating the proposal process when seeking GAVI Alliance support. It also explains in summary form GAVI's monitoring requirements and guides its users through the various forms used in the GAVI Alliance proposal and monitoring process. Users are directed to web-based resources where relevant, as well as to Annex 1 for a list of web-based sources of further information.

The GAVI Alliance's four strategic goals

- To contribute to strengthening the capacity of the health system to deliver immunisation and other health services in a sustainable manner;
- To accelerate the uptake and use of underused and new vaccines and associated technologies and improve vaccine supply security;
- To increase the predictability and sustainability of long-term financing for national immunisation programmes;
- To increase and assess the added value of GAVI as a public-private global health partnership through efficiency, advocacy, and innovation.

1.1 The GAVI Alliance

The GAVI Alliance mission is “saving children’s lives and protecting people’s health by increasing access to immunisation in poor countries.” Launched in 2000, the GAVI Alliance brings together developing world and donor governments, private sector philanthropists such as the Bill & Melinda Gates Foundation, the financial community, developed and developing country vaccine manufacturers, research and technical institutes, civil society organisations, and multilateral organisations, including the World Health Organization (WHO), the United Nations Children’s Fund (UNICEF) and the World Bank.

Principles of the GAVI Alliance

GAVI Alliance activities and financial support should:

- Contribute to achieving the Millennium Development Goals, focusing on performance, outcomes, and results;
- Promote equity in access to immunisation services within and among countries;
- Support nationally-defined priorities, budget processes, and decision-making;
- Be supportive of country participation through absence of earmarking;
- Focus on underused and new vaccines as opposed to upstream research and development activities;
- Contribute to the development of innovative models or approaches that can be introduced and applied more broadly;
- Be coherent with GAVI partners' individual institutional obligations and mandates;
- Be catalytic and time-limited, though not necessarily short term, and not replace existing sources of funding;
- Support activities that, over time, become financially sustainable or do not need to be sustained in order to have accomplished their catalytic purpose;
- Through market impact and innovative business models, render vaccines and related technologies more affordable for the poorest countries;
- Be based on accountability, transparency, efficiency, and effectiveness;
- Be consistent with the principles of harmonisation as agreed upon by OECD-DAC at the Paris High Level Forum.

The reach of each actor is enhanced through their partnership in the GAVI Alliance, which allows them as a group to set policy, devise strategy, and develop innovative solutions to problems that no one body would be able to overcome independently. The goals and principles that guide its activities and funding decisions are set out in the strategy document, *GAVI Alliance Strategy (2007–10)*, and are summarised below.¹

1.2 The GAVI Fund

The GAVI Fund is the financing arm of the GAVI Alliance.² The Fund attracts resources from a range of donors, including private philanthropists. The GAVI Fund has fiduciary responsibilities, including asset management and investment, financial control, auditing, and accounting over assets placed by donors within the GAVI Fund's control. This brings business and financial management insight into GAVI's activities, and thus the skills to manage resources effectively and channel funding where it is needed most.

¹ GAVI Alliance Strategy (2007-10)
http://www.gavialliance.org/resources/GAVI_Alliance_Strategy__2007_2010_.pdf

² The GAVI Fund is registered in the US as a 501(c)3 not-for-profit organisation.

³ For a more detailed description of IFFIm, please go to http://www.iff-immunisation.org/01_about_iffim.html.

1.3 The International Finance Facility for Immunisation

The International Finance Facility for Immunisation (IFFIm) is a new multilateral development institution created to accelerate the availability of predictable, long-term funds for health and immunisation programmes. IFFIm's financial base consists of legally binding grants payments from its sovereign sponsors, on the basis of which IFFIm issues AAA/Aaa/AAA-rated bonds in the international capital markets. The World Bank is the Treasury Manager for IFFIm. IFFIm's inaugural bonds of US\$ 1 billion were issued on 14 November 2006. IFFIm funds are provided as grants – not loans – through the GAVI Alliance in some 70 of the world's poorest countries.

IFFIm's anticipated investment of US\$ 4 billion over the next 10 years is expected to provide immunisation for an additional half a billion people, and avert as many as 10 million deaths. IFFIm was established as a charity with the Charity Commission for England and Wales and is registered in England and Wales as a company. By the end of December 2007, the seven governments of France, Italy, Norway, South Africa, Spain, Sweden, and the United Kingdom had committed funds to the IFFIm. Other donors are expected to follow suit. Brazil for example, has announced that it will pay \$ 20 million over 20 years.

IFFIm funding is being used, along with the annual direct contributions to the GAVI Alliance from its other donors, to fund the various GAVI Alliance programmes.³

Promoting the development and introduction of new vaccines

The GAVI Alliance is supporting Accelerated Development and Introduction Plans (ADIPs) for pneumococcal and rotavirus vaccines, as well as a special initiative to speed the introduction of *Haemophilus influenzae* type b (Hib) vaccine. The aim is to shorten the time lag between vaccines being proven safe and effective for use in the industrialised world and their introduction in developing countries.

GAVI's **PneumoADIP** is based at Johns Hopkins Bloomberg School of Public Health. It works in partnership with countries, researchers, donors, academia, international organisations, industry, and the media to establish and communicate the burden of pneumococcal disease and the potential benefits of vaccination. PneumoADIP's analyses supported two recent decisions that will accelerate access to life-saving pneumococcal vaccines by 10-15 years over historical precedents. Based on an investment case developed by PneumoADIP, the GAVI Alliance Board in 2006 added pneumococcal vaccines to the list of new and under used vaccines now available to eligible

countries, and in early 2007, a group of six major donors pledged US\$ 1.5 billion to a first-ever advance market commitment for accelerating access to and development of new pneumococcal vaccines. To learn more about the PneumoADIP, go to <http://www.preventpneumo.org>.

The **Rotavirus Vaccines Program** is housed at PATH. In partnership with WHO and the United States Centers for Disease Control and Prevention (CDC), this ADIP is demonstrating to governments the burden of rotavirus disease and the promise of existing and new vaccines to combat the disease. It is also working with countries and manufacturers to forecast worldwide demand and establish a consistent supply of available vaccines against this disease. The GAVI Alliance decision to begin offering rotavirus vaccine to countries in Latin America and Eastern Europe in 2006 is a direct result of the work of the **Rotavirus Vaccines Program** and its strategic partners, and work is under way to prove the vaccine's clinical efficacy in Africa and Asia as well. Read more about the **Rotavirus Vaccines Program** at <http://www.rotavirusvaccine.org>.

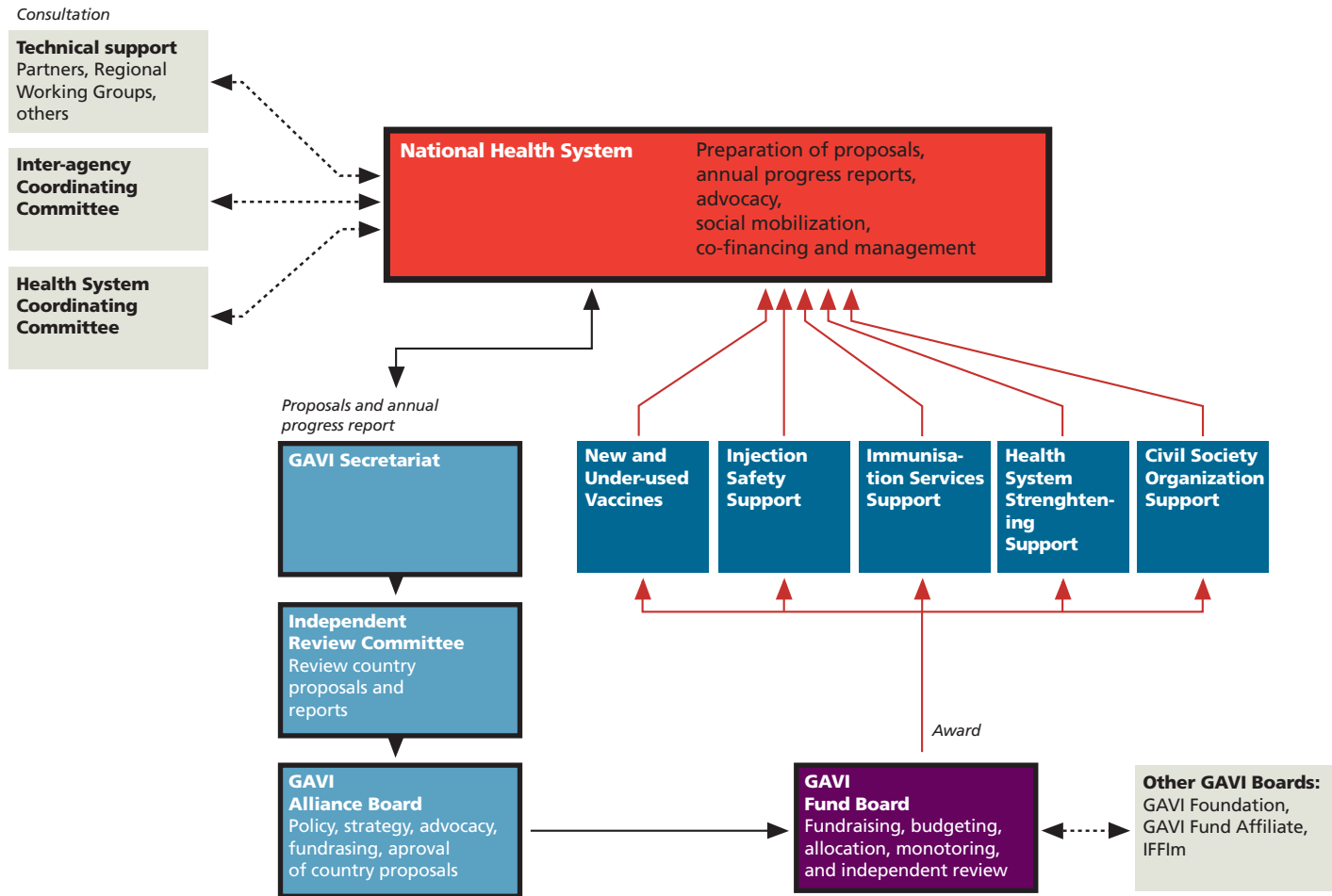
The **Hib Initiative** is a consortium that unites experts from Johns Hopkins Bloomberg School of Public Health (lead agency), the London School of Hygiene and Tropical Medicine, the United States Centers for Disease Control and Prevention, and WHO. The Hib Initiative's aim is to expedite and sustain evidence-informed decisions regarding the use of Hib vaccine to help prevent childhood meningitis and pneumonia. Country-focused efforts are in three areas: (i) strategic communication and advocacy, (ii) research and surveillance, including technical support, and (iii) funding for impact assessments and cost effectiveness analyses and coordination. By the end of 2007, 62 of 72 countries eligible for support had made a decision regarding the introduction of Hib vaccine and 47 countries had introduced or were approved to introduce the vaccine. This represents a more-than 60% increase in just two years. For further information, see the Hib Initiative website at <http://www.hibaction.org>.

1.4 The GAVI proposal and monitoring process

Countries with per capita gross national income (GNI) of US\$ 1,000 per year or less (based on 2003 estimates) are invited to submit a formal proposal for support to the GAVI Alliance Secretariat. GAVI requires governments to work with their interagency coordination committees (ICCs) and health sector coordination committees (HSCCs) in preparing their GAVI proposals and providing all the required documentation. GAVI's Independent Review Committee (IRC) reviews all proposals. When the IRC has reviewed a proposal, its chairperson passes the recommendation on to the GAVI Alliance

Board. Once the Board has given its approval, recommendations and funding requests are forwarded to the GAVI Fund Executive Committee, which then gives its approval for disbursement of funds or commodities. Decisions are communicated to the country by the GAVI Secretariat. Once approved, countries are required to submit annual progress reports (APRs). They must also successfully complete a data quality audit (DQA) during the ensuing period of support. Figure 1 illustrates the proposal, award, and reporting process that is described in more detail in the remainder of this Handbook.

Figure 1 **The GAVI proposal and monitoring process**



2

Who are the actors ?

- 2.1 Country governments 15
- 2.2 Interagency coordination committees 15
- 2.3 Health sector coordination committees 16
- 2.4 GAVI regional working groups 17
- 2.5 GAVI Alliance Secretariat 19
- 2.6 GAVI Independent Review Committee 20

- 2.7 GAVI Boards 21
 - 2.7.1 GAVI Alliance Board 21
 - 2.7.2 GAVI Fund Board 23
 - 2.7.3 GAVI Working Group 23



2 Who are the actors?

2.1 Country governments

Country governments are the heart of national health system strengthening and provision of immunisation and child health services. They play a crucial role in the GAVI-related processes outlined below.

*The **government** of an eligible country:*

- **decides** whether or not to apply for GAVI Alliance support and what types of support would be appropriate for its country;
- **receives** GAVI funds to strengthen health sector and immunisation service performance and chooses how those funds should be used;
- **calls and convenes** the interagency coordinating committee so that partners participate in the process of planning and monitoring progress in health sector and immunisation services strengthening;
- **leads** the relevant teams in preparing health sector strategic plans and the comprehensive multi-year plan;
- **invites** the data quality auditors to inspect its administrative system for routine immunisation reporting;
- **collects** information on relevant health sector indicators and immunisation coverage data and compiles annual progress reports for review by the interagency coordinating committee;

- **collects** the disease-burden data and other evidence needed to inform decisions on introducing new or underused vaccines into the country;

- **determines** the in-country process to engage civil society organisations in implementing health sector strategic plans and/or the country's GAVI Health System Strengthening (HSS) proposal.

2.2 Interagency coordination committees

Interagency coordination committees (ICCs) are composed of senior government and partner agency representatives, including international donors and organisations (both governmental and nongovernmental) involved in the process of developing or providing immunisation services in a given country. More than two-thirds of ICCs include civil society representation. ICCs may focus exclusively on immunisation or on a broader set of child or maternal/child health services. Most meet two to four times a year and are chaired by senior ministry of health officials. They may also have technical committees and subcommittees that meet more frequently. Interagency coordination committees

and their subcommittees facilitate the participation of governments and their external partners and perform a variety of functions in support of national immunisation programmes.

Among their GAVI-related duties, national **interagency coordination committees**:

- **review**, endorse, and sign country immunisation services support (ISS), new vaccine support (NVS), and injection safety support (INS) proposals for submission to the GAVI Secretariat;
- **participate** in preparing, signing, and submitting the country's annual progress reports to the GAVI Secretariat;
- **review** and monitor follow-up work to address any issues raised by the data quality auditors;
- **provide** a record of their deliberations in the minutes of each of their meetings;
- **review** the execution of annual work plans (which contain the objectives of each partner) prior to submission of the annual progress report to the GAVI Secretariat.

2.3 Health sector coordination committees

The health sector coordination committee (HSCC) or equivalent health planning group in each country is composed of senior representatives of government ministries and partner organisations (governmental, nongovernmental, and donor) that are involved in the health sector. The health sector coordination committee is usually chaired by the planning department in a ministry of health, or its equivalent, and coordinates activities across the health sector.

Among their GAVI-related duties, **the health sector coordination committees**:

- **guide** the ministry of health's department of health planning, or its equivalent, in the development of the country's health system strengthening (HSS) and civil society organisation (CSO) support proposals;
- **collaborate** with the national immunisation programme, other departments in the ministry of health, the ministry of finance, partners, and other key stakeholders in the development and implementation of the HSS and CSO proposals;
- **review, endorse, and sign** HSS and CSO proposals prior to their submission to the GAVI Secretariat;
- **participate** in preparing, signing, and submitting the country's annual progress reports to the GAVI Secretariat;

- **provide** a record of their deliberations in the minutes of each of their meetings;
- **reviews** the execution of annual work plans (which contain the objectives of each partner) prior to submission of the annual progress report to the GAVI Secretariat.

2.4 GAVI regional working groups

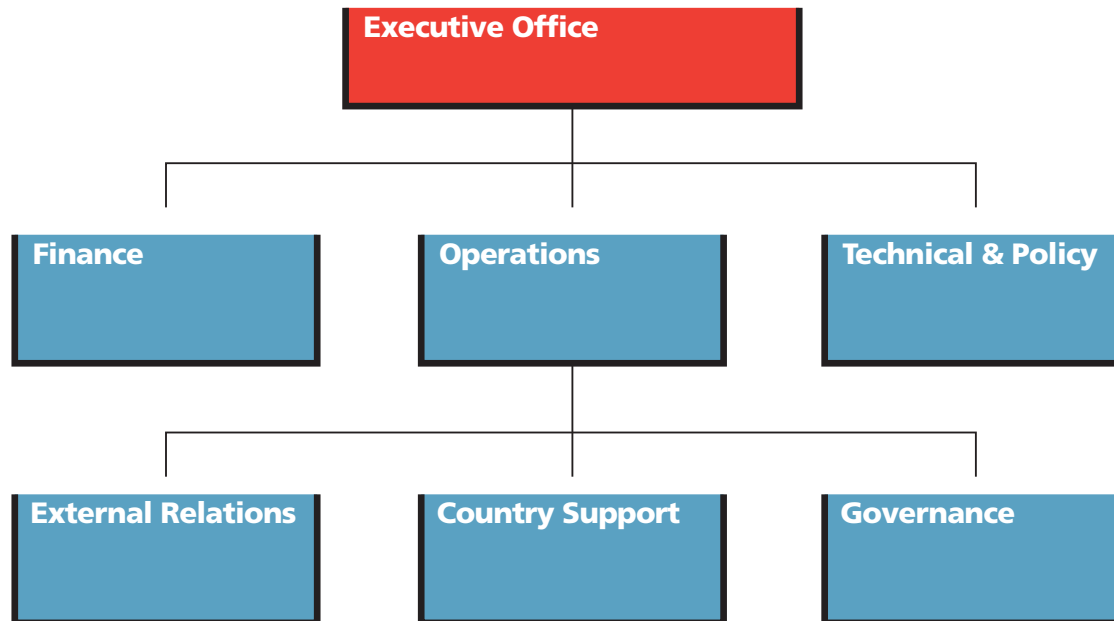
GAVI regional working groups (RWGs) are made up of the GAVI Alliance partner representatives who provide technical support to groups of countries and assist in representing the interests of those countries in GAVI's global decision-making processes. Regional working groups meet periodically during the year and perform a number of specific tasks.

Among their GAVI-related duties, **the regional working groups:**

- **provide** support, upon request, to countries in preparing proposals to the GAVI Alliance;
 - **review and provide** comments on changes in policies and procedures that are proposed by GAVI's global working group and task teams;
 - **review and provide** comments on countries' annual progress reports and other periodic performance monitoring reports that countries submit to the GAVI Alliance;
- **coordinate** technical assistance provided to national immunisation programmes by partners and/or their contractors;
 - **channel** information to national governments, especially on new policies or decisions.

Regional working groups can usually be contacted through the offices of GAVI Alliance partners in the respective country, alternatively the GAVI Alliance Secretariat can facilitate contact on request.

Figure 2 **Organisation of the GAVI Secretariat**



2.5 The GAVI Alliance Secretariat

The GAVI Alliance Secretariat is based in Geneva, Switzerland. The Secretariat links country requests for support with the GAVI Alliance and Fund boards and the related regional working groups. It organises the review – by the Independent Review Committee – of country proposals and annual progress reports. If any clarification is needed before proceeding with a proposal, the GAVI Alliance Secretariat takes responsibility for communicating directly with the country. The Secretariat is responsible for the day-to-day operations of the Alliance. It is led by the Executive Secretary and is supported by a number of teams, as shown in Figure 2.

The **Executive Office** is the strategic focal point for all Secretariat activities. The Executive Office supports the Executive Secretary in the oversight of GAVI Alliance policy and strategy, outreach to external stakeholders, supervision of the legal and financial operations of both the GAVI Alliance Secretariat and Fund offices, reporting to the GAVI Alliance and Fund Boards, and collaboration with Alliance partners and other global health partnerships.

The **Finance Team** guides the prudent investment of Alliance resources, manages consolidated, audited financial reporting across all GAVI entities, and establishes centralised internal controls and risk management. The Finance Team

also provides assistance in the design, negotiation, and implementation of innovative finance mechanisms for the GAVI Alliance.

The **Operations Team** develops and monitors the GAVI Alliance strategy and annual work plans. It manages human resources and the day-to-day operations of the Secretariat, oversees contracts and procurement activities, develops organisational policies and procedures, creates and manages Secretariat information and communication technology systems, and ensures clear communication channels across the Secretariat.

The **Technical and Policy Team** leads the process of new programme development by ensuring the engagement of all GAVI partners and leveraging their technical expertise. It evaluates programmes to make certain that all resources are used wisely and works with other teams to keep the boards and other decision-making bodies fully informed.

The **External Relations Office** guides GAVI's strategy for engagement with external partners. It includes teams for media and information, programme funding, private philanthropy and advocacy and public policy. The External Relations teams collectively lead all outreach to public and private donors, advocacy-oriented

civil society organisations, and work with media to raise the visibility of immunisation. The mission of the External Relations Office is to deliver a unified engagement strategy with key stakeholders of the GAVI Alliance – and through consistency of message and approach – ensure that GAVI’s role within the development community and beyond is understood and increasingly supported.

The **Country Support Team** processes requests for GAVI support, manages proposal review in collaboration with the Independent Review Committee, communicates outcomes to countries, and solicits country input for policy development. It also translates policy decisions into operational processes and communicates those processes to the countries. The team maintains a comprehensive database of country awards, requests, and achievements that is used to analyse trends, to highlight best practices and achievements, and to identify areas for further improvement.

The **Governance Team** works with GAVI Alliance staff and partners to set the strategic agenda for all Board and committee deliberations and to ensure transparency in all Board activities. It briefs Board members on policy issues and manages all communications to the Boards, provides outreach and support to individual partner constituencies, oversees development of all meeting documentation, and organises all governance meetings.

2.6 GAVI Independent Review Committee

With support from the Secretariat, and based on the pre-assessment teams’ reports, the Independent Review Committee (IRC) reviews new proposals and reports submitted by the countries and makes recommendations to the GAVI Alliance Board and the GAVI Fund Board. IRC members generally serve for a term of three years. When new members are needed, the GAVI Secretariat issues a call for nominations to its partners, specifying the particular area of expertise and qualifications needed. Members must be independent of the GAVI Alliance partners. Once nominations are submitted, the final decision is taken by the Executive Secretary.

The Independent Review Committee is composed of the following three teams that convene separately and at different times of the year:

- The New Vaccine, Injection Safety and Immunisation Services Support Proposal Review Team;
- The Health System Strengthening and Civil Society Organisations Proposal Review Team;
- The Monitoring Team.

2.7 GAVI boards

At the time of writing (December 2007), five GAVI boards perform specific governance functions. The two boards that are most concerned with support for GAVI-eligible countries are described here. For more information about the roles and responsibilities of these and the other GAVI boards, please go to <http://www.gavialliance.org/about/governance/boards>.

The GAVI governance structure is under review. At their November 2007 meeting, the GAVI Alliance and GAVI Fund boards agreed to a continued review and discussion about whether to merge the two boards into a unified, vertically integrated governance structure. The details of this new structure will be formally agreed at the end of February 2008. For the latest information on these developments, please see <http://www.gavialliance.org/about/governance/index.php>

2.7.1 The GAVI Alliance Board

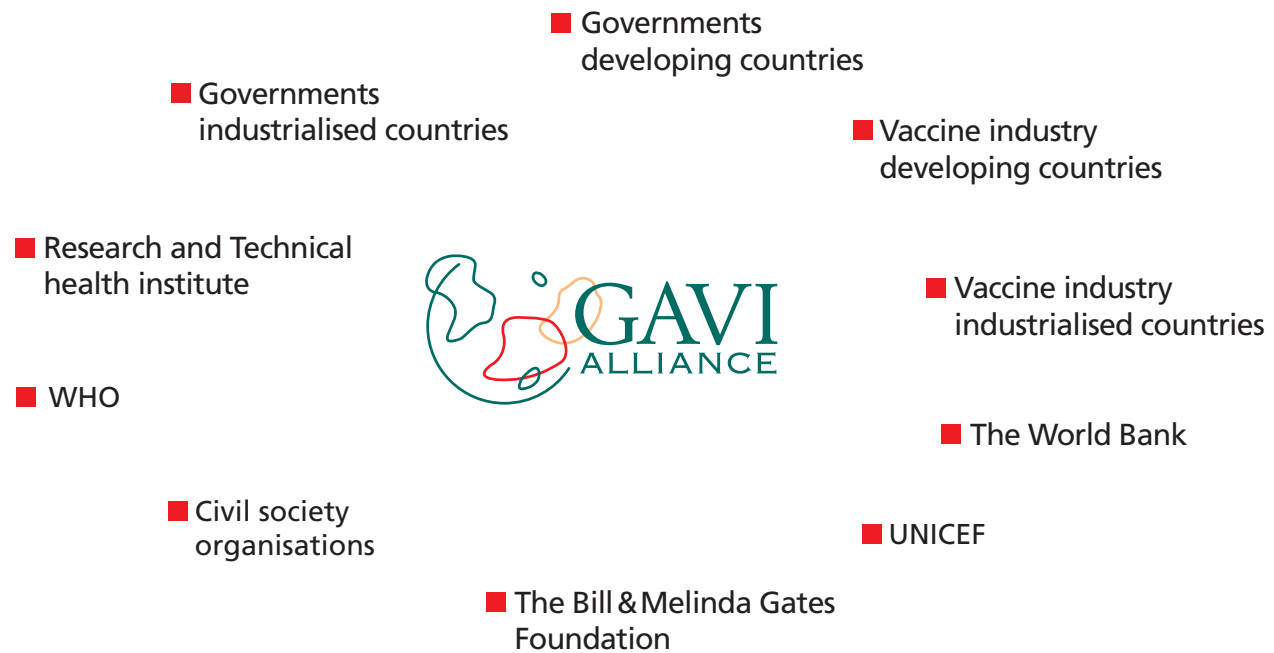
The GAVI Alliance Board comprises the highest-level representation from partners in immunisation. It has four renewable members: WHO, UNICEF, The World Bank, and the Bill & Melinda Gates Foundation. It also has 13 rotating members who represent the collective expertise and perspective of their respective constituencies, which include developing world and donor governments, developed and developing country

vaccine manufacturers, public health and research institutions, and civil society organisations (see Figure 3). The chair of the GAVI Alliance Board alternates between WHO and UNICEF.

The GAVI Alliance Board:

- **shapes** the Alliance's strategic vision and direction;
- **provides** highest-level policy decisions, ensuring alignment in Alliance partner activities;
- **reviews**, approves, and provides guidance on the GAVI Alliance Strategic Plan and work plans;
- **considers** the recommendations of the Independent Review Committee, approves support for country immunisation programmes, and requests funds to be disbursed by the GAVI Fund;
- **notes and monitors** the commitments of partners to undertake certain strategies and activities;
- **approves** the work plans and budgets of the Secretariat and any task force that might be established by the Board;
- **contributes**, through its members, to fund-raising and advocacy activities;
- **appoints** the Executive Secretary and submits his/her name to the host organisation for appointment;
- **resolves** issues among partners.

Figure 3 **The GAVI Alliance Board composition**



A GAVI Alliance Executive Committee was created in 2003 to enhance the strategic decision-making abilities of the GAVI Alliance Board. The Executive Committee – the representatives of which come from the same stakeholder groups as the GAVI Alliance Board – oversees policy development and implementation. It is also authorised to make critical, time-sensitive decisions between GAVI Alliance Board meetings.

2.7.2 The GAVI Fund Board

The GAVI Alliance Board and the GAVI Fund Board work hand-in-hand to establish the Alliance's strategic direction and to ensure that the resources are available to support its programmes. The GAVI Fund Board brings valuable private sector expertise and approaches to child health and immunisation challenges. It also sets financial policies and strategies and oversees areas related to fund-raising and fiduciary control over assets provided by donors to the GAVI Fund. In doing so, it helps to ensure that programmatic decisions are informed by sound financial analysis, bringing transparency, accountability, and value-for-money to all of GAVI's activities.

The GAVI Fund Board monitors GAVI income, certifies the availability of funding, and decides which funding source will be used to support country programmes, purchases vaccines in support of those programmes, and carries out

other activities. The GAVI Fund Board establishes the framework for monitoring and periodic evaluation of financial performance and accountability of activities supported by the GAVI Alliance. Like the GAVI Alliance Board, the GAVI Fund Board also has an executive committee that meets regularly.

2.7.3 The GAVI Working Group

The GAVI Working Group is responsible for helping to monitor implementation of the decisions of the GAVI Alliance Board, and comprises technical experts from GAVI partner institutions. In this capacity, the Working Group contributes to the development of the GAVI Alliance work plan, supports the Secretariat in the preparation of policy recommendations for Board consideration, and ensures close coordination of partner activities. The Working Group, which is chaired by the GAVI Alliance Executive Secretary, meets at least once each quarter and holds teleconferences every two weeks or as needed. Its members serve in an individual, non-institutional capacity.

Question & answer

To whom should countries go to when they need help with their applications and reports to the GAVI Alliance?

Countries can use a range of sources of information and technical support during their preparation of proposals and reports:

- The GAVI Secretariat's **Country Support Team**⁴ is available to respond to specific questions about GAVI Alliance support, proposal guidelines, and other Alliance requirements.
- Members of the **interagency coordinating committee and health sector coordination committee** often provide countries with technical support for proposal preparation and report writing.
- The **GAVI regional working groups**, which include representatives from organisations such as WHO and UNICEF, provide both direct support to countries and assistance in identifying appropriate consultants.

- **Peer review** of draft proposals by groups of stakeholders and technical experts is a common practice to ensure that country proposals are complete and ready for submission.

- Upon request, the **GAVI Alliance Independent Review Committee** is available to pre-screen country proposals prior to their formal submission.

- For health system strengthening (HSS) proposal development, a **one-time grant of up to US\$ 50,000** may be requested by the health sector coordination committee, ministry of health planning divisions, or their equivalent. The recently revised HSS guidelines⁵ provide a list of the activities that qualify for this funding.

Countries are encouraged to take advantage of one or more of these possible sources of technical support.

⁴ For more information, please see <http://www.gavialliance.org/about/governance/secretariat/index.php>

⁵ Revised guidelines for: GAVI health system strengthening support (HSS applications). Geneva, GAVI Alliance, 2007, available at http://www.gavialliance.org/resources/HSS_Guidelines_2007.pdf

3

What types of support does GAVI offer?

- 3.1 Immunisation services support 29
 - 3.1.1 What does the GAVI Alliance provide? 29
 - 3.1.2 What are the conditions for immunisation services support? 31
 - 3.1.3 How long does immunisation services support last? 31
- 3.2 New and underused vaccines support 32
 - 3.2.1 What does the GAVI Alliance provide? 32
 - 3.2.2 What are the conditions for support? 34
 - 3.2.3 Co-financing new and underused vaccines 35
 - 3.2.4 Prioritisation of vaccine products supplied by GAVI 38
 - 3.2.5 How long does new vaccine support last? 39
- 3.3 Injection safety support 39
 - 3.3.1 What does the GAVI Alliance provide? 39
 - 3.3.2 What are the conditions for injection safety support? 40
 - 3.3.3 How long does injection safety support last? 40
- 3.4 Health system strengthening support 40
 - 3.4.1 What does the GAVI Alliance provide? 41
 - 3.4.2 What are the conditions for HSS support? 42
 - 3.4.3 How long does HSS support last? 42
- 3.5 Civil society organisation support 43
 - 3.5.1 What does the GAVI Alliance provide? 45
 - 3.5.2 What are the conditions for CSO support? 45
 - 3.5.3 How long does CSO support last? 47



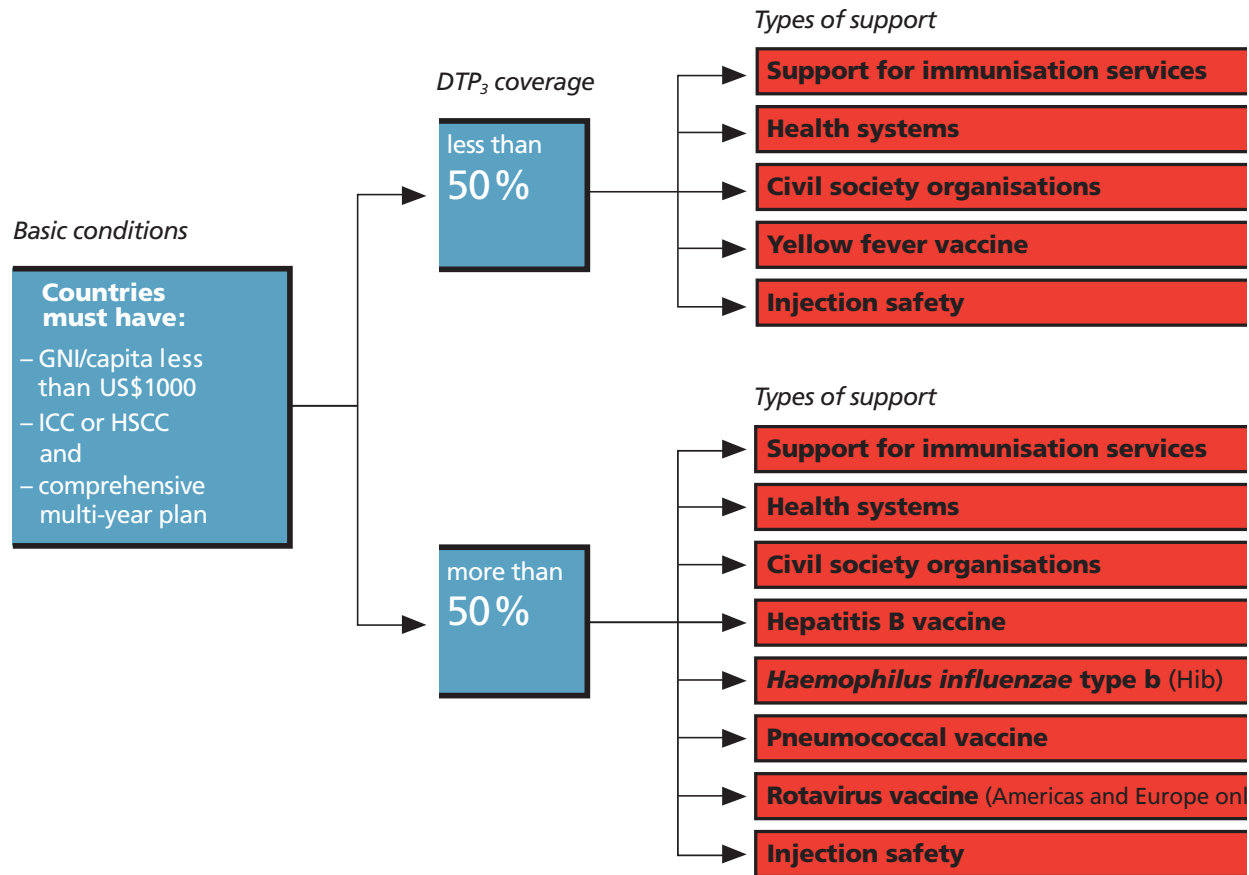
3 What types of support does GAVI offer?

The GAVI Alliance offers five types of support:

- immunisation services support;
- new and underused vaccines support, which is provided with associated injection safety equipment and a vaccine introduction grant;
- injection safety support;
- health system strengthening support;
- civil society organisation support.

Any country that has a per capita gross national income (GNI) below US\$ 1,000 (based on 2003 estimates) is eligible to apply for GAVI support. Figure 4 shows the basic conditions that apply to the provision of each type of support and the way that support is differentiated according to whether a country has DTP₃ coverage below or above 50%. Countries have the opportunity to request technical support for proposal development through GAVI Alliance partners such as WHO and UNICEF.

Figure 4 **Basic conditions for GAVI Alliance support**



3.1 Immunisation services support

3.1.1 What does the GAVI Alliance provide?

Immunisation services support, also referred to as GAVI ISS, is financial support provided to national governments for the development of their immunisation services.

The GAVI Alliance does not prescribe conditions for the use of immunisation services support. Rather, it imposes strict requirements for performance, relying on governments and interagency coordinating committees to set goals, to develop plans for the use of the support, and to monitor progress.

To stimulate increases in routine immunisation coverage, immunisation services support provides an incentive of US \$ 20 for each additional child vaccinated with three doses of DTP (the diphtheria–tetanus–pertussis vaccine) compared with the previous year. The amount of funding a country receives each year thus depends on its annual performance.

Immunisation services support is provided in two distinct phases, beginning in the year of funding approval and continuing in the following manner:

- **Investment phase:** During the first and second years following approval of the first immunisation services support proposal, GAVI support is considered to be an “investment” in the effort that will be needed to raise coverage and meet planned immunisation targets in the future.
- **Reward phase:** From the third year after approval to the year after the end of the comprehensive multi-year plan (cMYP), immunisation services support is treated as an incentive and calculated according to country achievements in surpassing previous year immunisation targets. Continuation of the reward phase of immunisation services support depends on strict performance monitoring and increasing the numbers of children immunised each year.

To further understand how these principles of support are applied, see the explanation below and the example provided in Annex 2 of this Handbook.

How GAVI immunisation services support is calculated

To calculate the amount of immunisation services support a country will receive during the investment and reward phases, GAVI uses a **performance indicator** and a **baseline** that changes according to the year of support.

■ Investment phase – (years 1 and 2 for countries that have not received immunisation services support in the past)

Indicator of prospective performance = number of additional children less than one year of age targeted to receive the DTP₃ vaccine in the first year following approval of GAVI support, compared with the initial baseline.

Initial baseline = number of children less than one year of age who received DTP₃ vaccine in the year before GAVI's approval of the country proposal.

Investment calculation = Indicator of prospective performance x US\$ 20.

Investment is disbursed in three portions:

1. 25% paid immediately after the approval of ISS proposal;
2. 25% paid after the country submits its first satisfactory annual progress report;
3. 50% paid after the country submits its second satisfactory annual progress report.

■ Reward phase (beginning in the third year of immunisation services support)

To qualify for rewards, countries must increase the numbers of children receiving the DTP₃ vaccine each year and they must have completed a successful data quality audit.

Performance indicator in the reward phase = number of additional children less than one year of age who received the DTP₃ vaccine in a 12-month period, compared with a baseline.

Baseline for the first reward = number of children less than one year of age who were targeted to receive the DTP₃ vaccine in the first year after GAVI's approval of the country proposal.

Baseline for subsequent rewards = number of children less than one year of age who were reported to have received the DTP₃ vaccine in the previous year (or the year of highest DTP₃ achievement since the initial baseline year).

Reward calculation = Performance indicator x US\$ 20.

Rewards are paid each year, starting in the third year after ISS approval, once the country submits a satisfactory annual progress report.

Countries are eligible to continue receiving rewards until the final year of their cMYP. They may then reapply for immunisation services support with a new cMYP; those approved will be eligible for rewards only during their second award period.

3.1.2 What are the conditions for immunisation services support?

Any GAVI-eligible country can apply for immunisation services support. The basis for an immunisation services support proposal is the country's comprehensive multi-year plan (cMYP) for immunisation. The immunisation services support proposal should reflect the coverage targets in the country's cMYP for immunisation and should describe its plans for achieving those targets. It should also describe how funding will be managed. All country proposals for immunisation services support should be developed by governments in consultation with their interagency coordinating committees or equivalent coordination mechanisms.

To qualify for immunisation services support rewards starting in the third year after approval, countries must show that they have increased the number of children vaccinated over the investment phase. In addition, they must have successfully conducted a data quality audit (DQA)⁶ to show that their immunisation reporting system is robust. The DQA is managed by external auditors who are contracted directly by the GAVI Secretariat.

All countries that reapply for immunisation services support after the first immunisation services support grant are required to complete a second DQA a year after approval of the new immunisation services support or four years after

the last successful DQA, whichever is sooner. This arrangement affords countries the opportunity to make improvements in their management information systems and also reassures GAVI and other stakeholders of the continuing reliability of the country data.

3.1.3 How long does immunisation services support last?

GAVI provides two years of investment shares and will continue providing reward shares in subsequent years until the end of the country's comprehensive multi-year plan. Countries reapplying for immunisation services support will not receive a second investment but will continue to receive rewards.

The following guidelines and country application forms, alongside additional reference materials for immunisation services support can be found on the GAVI Alliance website:⁷

- *Guidelines for ISS, INS, and NVS*, available in English, French, and Russian.
- *Application form for ISS, INS, and NVS*, available in English, French, and Russian.

⁶ How to prepare for a data quality audit. Briefing Paper. Geneva, GAVI Alliance, 2002, available at <http://www.gavialliance.org/resources/DQABriefPaper02.pdf>

⁷ All GAVI support guidelines are available at <http://www.gavialliance.org/support/how/guidelines/index.php>

Question & Answer

What are acceptable sources for a country's initial baseline figure?

The WHO/UNICEF Joint Reporting Form⁸ numerator for reported DTP₃ immunisation is the only source normally accepted by GAVI. GAVI does not accept subsequent changes to the initial baseline figure.

Question & Answer

If a country doesn't meet its targets in the first or second year, will GAVI reduce or interrupt the grant?

No, GAVI establishes the overall grant for the first two years and pays it in three portions – immediately after the award, following the receipt of a satisfactory inception report (usually in the first year after approval), and following receipt of the first annual progress report (usually in the second year after approval).

⁸ The WHO/UNICEF Joint Reporting Form may be downloaded (in English or French) from http://www.who.int/immunization_monitoring/routine/joint_reporting/en/index.html. In 2007, the DTP₃ numerator referred to above is to be reported on: Tab 4A. Routine Immunization, row 4040, column C.

⁹ WHO's position paper on *Haemophilus influenzae* type b conjugate vaccines is available at http://www.who.int/immunization/REH_47_8_pages.pdf

3.2 New and underused vaccines support

3.2.1 What does the GAVI Alliance provide?

Vaccines

GAVI provides vaccines and associated injection equipment to countries that meet the immunisation coverage criteria (as laid out in Figure 4), as well as the specific conditions for the type of vaccine requested. These conditions relate mainly to the use of a specific antigen in relation to the disease burden it is designed to prevent, and are as follows:

- **Hepatitis B antigen** is accepted for use in all eligible countries.
- ***Haemophilus influenzae* type b antigen (Hib)** is now recommended for introduction in all routine infant immunisation programmes by WHO's Strategic Advisory Group of Experts (SAGE), which says that "Lack of local surveillance data should not delay the introduction of the vaccines, especially in countries where regional evidence indicates a high burden of disease."⁹
- **Yellow fever antigen** is appropriate for routine use in yellow fever-endemic areas of Africa and the Americas, according to regional recommendations, regardless of DTP₃ coverage. The GAVI Alliance will contribute to topping-up existing government financial commitments to yellow fever vaccination, where it is already

part of a routine immunisation programme and where yellow fever immunisation coverage is lower than that for measles.

- **Pneumococcal** vaccine is accepted by WHO for use in all GAVI-eligible countries. Vaccine supply is currently limited, but it will increase as new manufacturers begin production. The first applications for pneumococcal vaccine were approved by the GAVI Alliance Board in November 2007.
- **Rotavirus** vaccine is currently accepted for use in the Americas and Europe, where it has been shown to protect infants and children in randomised, placebo-controlled efficacy studies. Work is ongoing to secure Studies are ongoing to assure safety and efficacy of rotavirus vaccine in other regions. The first applications for rotavirus vaccine were approved by the GAVI Alliance Board in November 2007.
- **Measles second dose** vaccination support will be provided by the GAVI Alliance if it is included in the country's comprehensive multi-year plan. Countries can re-apply for measles second dose support as often as a new comprehensive multi-year plan is developed, up to a limit of five years, but not beyond 2015. The application for this support must be endorsed by WHO.

Only vaccines that are prequalified by WHO can be bought with GAVI funds.

Calculation of vaccine needs

Forecasting: GAVI bases its calculation of vaccine needs on a target population for a specific year, with adjustments for anticipated wastage rates and balance of stock. GAVI requires that: for vaccines requiring multiple contacts, the coverage of the first – rather than the last – dose be used to estimate the target population.

Vaccine wastage: GAVI accepts a maximum wastage rate of:

- 50% for a freeze-dried vaccine in a 10- or 20-dose vial;
- 25% for a liquid vaccine in a 10- or 20-dose vial;
- 10% for a lyophilised vaccine in a 2-dose vial; and
- 5% for a liquid vaccine in 1-dose vial.

Buffer stocks: The buffer stock requirement is normally 25% for the first year that the vaccine is introduced into any given geographical area. The quantity of buffer stock should be adjusted annually according to actual stock balances, so that it continues to equal 25% on top of the requirement for the coming year.

Vaccine introduction grants

When approved for new vaccine support, countries will also receive a one-time cash grant to cover the additional costs related to new vaccine introduction and to fund critical pre-introduction activities. This grant might be used to finance training, public information and social mobilisation, cold chain upgrade and maintenance, vaccine delivery, printing and purchase of materials (such as immunisation cards), surveillance, and other activities associated with the introduction of a new vaccine. The vaccine introduction grant cannot be used for vaccine co-financing.

The vaccine introduction grant will be a minimum award of US\$ 100,000 and a maximum of US\$ 0.30 per infant in the birth cohort of the year of vaccine introduction. Although the vaccine introduction grant is a one-time award, it will be provided for each vaccine awarded to a country through the GAVI new and underused vaccine support window, including when a country switches vaccine presentation of the same antigen.

In order to obtain this grant, countries must define the activities they will carry out in preparing for vaccine introduction, develop a detailed budget for the full non-vaccine costs of introducing the new vaccine or vaccine product, and indicate for which activities the grant will be used. This plan should be used to seek resources

from national authorities or other partners in the event that the GAVI new vaccine introduction grant is not sufficient to meet all requirements. The new and underused vaccine application form contains specific tables that must be completed in order to be awarded the vaccine introduction grant.

3.2.2 What are the conditions for new vaccine support?

Governments applying for new and underused vaccine support must agree to co-finance the vaccine from the onset of support. This excludes support for the introduction of a second dose of the measles vaccine. GAVI Alliance co-financing policies are explained further in section 3.2.3.

A comprehensive multi-year plan for immunisation¹⁰ must be submitted with each proposal for new and underused vaccine support. It must:

- be valid for at least two years from the date of proposal;
- be based on a situation analysis of the current system;
- be aligned with the health sector plan and the health planning and budgeting cycles;
- include information on the estimated burden of disease and impact of the new vaccine where WHO says this is essential in the process of vaccine introduction;

¹⁰ For more information about planning and financing national immunisation programmes, go to http://www.who.int/immunization_financing/tools/cmyp/en/index.html.

- include an analysis of cost-effectiveness in the national context and the country's ability to co-finance the vaccine;
- include a plan for the introduction of the new vaccine(s)¹¹;
- include a plan for controlling vaccine waste and reducing immunisation drop-out rates;
- include a plan for improving injection safety in the immunisation system;
- include costing and financing plans for vaccine purchase and immunisation services.

Question & answer

If a country procures its vaccines or injection safety supplies independently, can it apply to GAVI for reimbursement?

Yes, if it has a fully functional national regulatory authority that complies with WHO- and UNICEF-recommended procedures for vaccine procurement. Countries must procure vaccines from WHO prequalified manufacturers. GAVI will provide reimbursement after the vaccine has been purchased. The reimbursement will be equivalent to the value of the UNICEF price for the same vaccine supplies. A country that pays more than the UNICEF price will be responsible for the difference.

3.2.3 Co-financing new and underused vaccines

The GAVI Alliance requires that all countries make a minimum co-financing contribution towards the cost of the introduction of a new or underused vaccine. The objective of co-financing is to encourage rigorous national decision-making and to help countries strive for financial independence. This is particularly important because GAVI Alliance support is time-limited.¹²

The anticipated cost of a new vaccine and the co-financing that each country will contribute should be included in the country's comprehensive multi-year plan for immunisation (see section 3.2.2) and in its relevant national planning and budgeting documents.

While all countries are expected to co-finance the new vaccines support they receive at the minimum levels listed in Table 1, higher contributions are encouraged. Increasing country contributions each year can be an important step towards financial sustainability, irrespective of future GAVI support. Countries in the 'Least poor' group are expected to increase their annual co-financing levels by annual increments of at least 15% of the previous year's co-financing amount (see Table 2).¹³

¹¹ If a country's current cMYP does not include a plan for introduction of the new vaccine(s) it is requesting, such a plan may be submitted as an annex, but like the cMYP, it must be endorsed by the government and its interagency coordination committee partners.

¹² The GAVI Alliance and GAVI Fund recognise that for some countries, financial independence may not be achieved by 2015.

¹³ For more information on GAVI Alliance co-financing policy, see New Vaccines Co-financing Q & A at http://www.gavialliance.org/resources/Co_financing_QA_en.pdf

Table 1

Co-financing levels, 2007–2010 (in US \$, minimum amount per dose of vaccine¹⁴)

Vaccine	Examples	GAVI country group			
		Poorest	Intermediate	Least poor	Fragile states
No. 1	1st vaccine, single or combination vaccines (including yellow fever)	0.20	0.30	0.30 (+15% annually)	0.10
No. 2	2nd additional vaccine (single or combination)	0.15	0.15	0.15 (+15% annually)	0.15
No. 3	3rd additional vaccine (single or combination)	0.15	0.15	0.15 (+15% annually)	0.15

Question & answer

How do we determine co-financing for rotavirus vaccine, which is available in both a 2-dose and a 3-dose presentation?

For rotavirus vaccine, the co-financing levels are the same regardless of presentation. An adjustment factor has been added in annex 2 of the new vaccine application form to aid the calculation of the appropriate co-financing levels for rotavirus vaccine for the country. This will be reviewed following the initial experience.

Question & answer

Are there any exceptions to the co-financing policy for new vaccines?

Only one. Countries are not expected to co-finance measles second dose introduction. They are, however, required to provide evidence of technical advice from WHO recommending its introduction. Support for the measles vaccine is in the form of cash, equivalent to the cost of measles vaccine doses and injection safety material, based on the UNICEF Supply Division price, and includes freight

and insurance charges. A country can use the funds to contribute to the purchase of a second dose measles vaccine presentation of their choice, either monovalent or combined with other vaccines. It is anticipated that most countries will procure the measles vaccine from UNICEF Supply Division. However, countries can procure the vaccine from an alternative supplier, if the selected manufacturer is WHO prequalified and complies with WHO recommended procedures.¹⁵

¹⁴ The co-financing cost is for each additional vaccine and includes vaccine and syringe unit costs, insurance, freight, and overhead costs.

¹⁵ WHO requires that the manufacturer produce the vaccines under the regulatory supervision of an agency assessed by WHO and certified to meet all WHO requirements for a national regulatory authority in a vaccine-producing country.

Table 2

GAVI Alliance country groups and corresponding co-financing policies

Group ^a	Country	Definition ^b	Co-financing policy
Poorest	Bangladesh, Benin, Bhutan, Burkina Faso, Cambodia, Chad, Comoros, Ethiopia, Gambia, Guinea, Guinea-Bissau, Lao People's Democratic Republic, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, United Republic of Tanzania, Togo, Uganda, Yemen, Zambia	<ul style="list-style-type: none"> – Latest GNI under US\$ 1,000 per capita. – Classified by the United Nations as a LDC country. 	<ul style="list-style-type: none"> – Until 2010, all countries will pay a minimum fixed co-financing amount per dose of the chosen vaccine. – This amount will increase after 2010, depending on the estimated future price of the chosen vaccine.
Intermediate	Cuba, Ghana, India, Kenya, Democratic People's Republic of Korea, Kyrgyzstan, Republic of Moldova, Mongolia, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Tajikistan, Uzbekistan, Viet Nam, Zimbabwe	<ul style="list-style-type: none"> – Latest GNI under US\$ 1,000 per capita. – Not classified by the United Nations as a LDC country. 	<ul style="list-style-type: none"> – Until 2010, all countries will pay a minimum fixed co-financing amount per dose of the chosen vaccine. – This amount will increase after 2010, depending on the estimated future price of the chosen vaccine. – The minimum co-financing level will be higher than that of the poorest group.
Least poor	Armenia, Azerbaijan, Bolivia, Cameroon, Djibouti, Georgia, Guyana, Honduras, Indonesia, Kiribati, Sri Lanka, Ukraine	<ul style="list-style-type: none"> – Latest GNI over US\$ 1,000 per capita. – All countries will pay a co-financing amount that gradually increases towards a target in 2015, consistent with the estimated future price of the chosen vaccine. 	<ul style="list-style-type: none"> – The minimum co-financing levels will start at a level higher than that of the intermediate group co-payment level.
Fragile	Afghanistan, Angola, Burundi, Central African Republic, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Eritrea, Haiti, Liberia, Sierra Leone, Somalia, Sudan, Timor-Leste	<ul style="list-style-type: none"> – GAVI Alliance eligible country meeting the GAVI Alliance fragile state criteria. – Until 2010, all countries will pay a fixed co-financing amount per dose of the chosen vaccine, but with flexible payment terms. 	<ul style="list-style-type: none"> – This amount will increase after 2010, depending on the estimated future price of the chosen vaccine. – The minimum co-financing level will be lower than that of the poorest group.

GNI gross national income
LDC least developed country

^a Designation of countries by GAVI group as of November 2007.

^b The United Nations classification for "least developed countries (LDC)" is based upon three criteria: 1) low-income criterion; 2) human resource weakness criterion; and 3) economic vulnerability criterion. The criteria (and the countries) are re-evaluated every three years. GAVI defines fragile states as countries eligible for international development aid post-conflict allocation and countries in conflict.

3.2.4 Prioritisation of vaccine products supplied by GAVI

The market for vaccine products funded by GAVI is evolving. For hepatitis B (Hep B) and *Haemophilus influenzae* type b (Hib) vaccines, until 2006 countries had to choose between monovalent products and three types of combination vaccines. Because some of those products were in limited supply, GAVI developed a policy to prioritise the access to different types of products.

This policy applies both to countries that have been approved for one type of vaccine product and are about to introduce it and also to countries that would like to switch from one type of product to another.

The general principles set forth in the policy are:

- countries receiving one type of vaccine product should be guaranteed a supply of their preferred product for the duration of the support they will be receiving from the GAVI Alliance;
- countries that have not introduced the new vaccine (new approvals) will receive first priority;
- countries with lower DTP₃ coverage will receive second priority on the basis that those countries with weak immunisation systems are those that have the greatest programmatic and safety considerations to overcome;
- for countries that meet the above criteria equally, vaccine products will be allocated in the order that the proposals or requests are received.

Question & answer

How does prioritisation of new vaccine products affect countries with large birth cohorts?

Worldwide, the production of some vaccine products is still very limited. This is why, when a country with a large birth cohort applies for a new vaccine, even though its request is approved, its preferred vaccine

product may not be available for some time. To increase the chances that countries with large populations receive at least some of their preferred vaccine products, they may wish to consider requesting several different products from the start. This would ensure that their citizens benefit from a new antigen in the

short term, and avoids risking having to delay vaccine introduction until the preferred vaccine product becomes available in sufficient quantities. As vaccine production increases, rationing of vaccine supplies will become less of a problem.

3.2.5 How long does new vaccine support last?

Countries will receive new and underused vaccine support through to the end of the last year of their comprehensive multi-year plans. Countries may reapply for continuation of new and underused vaccine support or for another new or underused vaccine once a new comprehensive multi-year plan has been developed.

The following guidelines, country application forms, and reference materials for new and underused vaccine support can be accessed via the GAVI Alliance website:¹⁶

- *Guidelines for ISS, INS, and NVS*, available in English, French, and Russian.
- *Application form for ISS, INS, and NVS*, available in English, French, and Russian.
- *Calculation of required NVS support, excluding rota and pneumo vaccines*, available in English, French, and Russian.
- *Calculation of required NVS support – rota and pneumo vaccines*, available in English, French, and Russian.
- *Guidelines for prioritisation of vaccine products supplied by GAVI*, available in English and French.
- *New vaccines co-financing Q&A*, available in English.

3.3 Injection safety support

3.3.1 What does the GAVI Alliance provide?

The purpose of injection safety support from the GAVI Alliance is to provide first-time safe injection and waste disposal supplies for routine immunisation to those countries that have not yet received them. To be eligible for injection safety support, a country must already be receiving (or be approved to receive) at least one of the other forms of GAVI support.

The maximum support the GAVI Alliance offers for injection safety is equivalent to the cost (at prices obtained by UNICEF) of auto-disable syringes and safety boxes for use with injectable vaccines (e.g. BCG, measles, DTP, TT, and polio, where it is used). The annual quantities required are calculated according to the WHO Expanded Programme on Immunization vaccination schedule for infants over a three-year period.

For procurement of the supplies, countries can choose either to receive the auto-disable syringes and safety boxes in kind from GAVI (procured through UNICEF), or to receive an equivalent cash grant.

¹⁶ All GAVI support guidelines are available at <http://www.gavialliance.org/support/how/guidelines/index.php>.

3.3.2 What are the conditions for injection safety support?

All countries applying for injection safety support must have a national policy on injection safety, and a strategic or action plan for improving injection safety and safe management of sharps waste in their immunisation systems. The appropriate sections of the country's comprehensive multi-year plan for immunisation which describe these policies and/or plans should be included with country proposals to the GAVI Alliance for injection safety support.

3.3.3 How long does injection safety support last?

Applications for injection safety support are accepted by the GAVI Alliance in relation to vaccines that are already part of a country's national immunisation schedule. In this case, injection safety support covers a period of up to three years for each eligible vaccine. At the end of the three-year period, countries are expected to make the transition to full national financing.

In addition to injection safety supplies for vaccines that are already part of the national immunisation schedule, countries approved to receive a new vaccine will receive autodisable syringes and safety boxes as part of the package. In this case, a separate injection safety application is not required and support will continue for the period of the new vaccine support.

Guidelines and application forms for injection safety support may be downloaded from the GAVI Alliance website¹⁷.

Look for:

- *Guidelines for ISS, INS, and NVS*, available in English, French, and Russian.
- *Application form for ISS, INS, and NVS*, available in English, French, and Russian.

3.4 Health system strengthening support

The objective of GAVI health system strengthening support is to achieve and sustain increased immunisation coverage, through strengthening the capacity of the health system to provide immunisation and other health services. Countries are encouraged to use GAVI health system strengthening funding to target the "bottle-necks" or barriers in the health system that make it difficult to improve the provision of, and demand for, immunisation and other child and maternal health services.

¹⁷ All GAVI guidelines are available at <http://www.gavialliance.org/support/how/guidelines/index.php>.

3.4.1 What does the GAVI Alliance provide?

GAVI provides country governments with funds to address identified barriers that are known to impede the demand for, and the delivery of, immunisation and other maternal and child health services. GAVI health system strengthening support cannot be used to purchase vaccines. GAVI's mechanism of support for new and underused vaccines is reserved for this purpose (see section 3.2).

GAVI health system strengthening funds are allocated to countries on the basis of the annual number of births and GNI per capita. Countries with a latest GNI¹⁸ figure of less than US\$ 365 per capita can receive up to US\$ 5 per newborn child per year during the period of the proposal. Countries with a latest GNI figure of \$ 365 per capita or more can receive up to US\$ 2.50 per newborn child per year.

GAVI recommends that countries use health system strengthening support to work on three priority areas:

- **health workforce mobilisation**, distribution, and motivation targeting personnel engaged in immunisation and other health services at the district level and below;
- **organisation and management of health services** at the district level and below (including financial management);
- **supply, distribution, and maintenance systems for drugs, equipment, and infrastructure** for primary health care.

These areas are *not* intended to be exclusive: GAVI health system strengthening can target one or all three of these areas *or any other area(s)* that impedes the delivery of immunisation and other child and maternal health services, *as long as the proposal shows how it will improve and/or help sustain immunisation coverage in the country.*

GAVI health system strengthening support focuses on service delivery and impact at the subnational level, but recognises that national functions (for example, commodity procurement, storage and distribution, financial management, and health information systems) are also essential for the provision of services at the subnational level. Therefore, activities at national level will be accepted for support as long as proposals clearly show how they will lead to increased and sustained immunisation coverage.

The GAVI Alliance will provide countries that require technical support during the health system strengthening application process with a one-time grant of not more than US\$ 50,000. Requests for technical support grants must describe the nature of the support required, include a budget, and indicate the preferred

¹⁸ In this case, "latest" refers to the year prior to disbursement of the current year's health system strengthening support.

account or agency through which funds should be channelled to the country. Users of this Handbook are advised to contact the GAVI Alliance Secretariat's Country Support Team/ Health System Strengthening Team Leader for more information about a possible HSS technical support grant (see Annex 4 for contact details).

3.4.2 What are the conditions for health system strengthening support?

The proposal development for health system strengthening support must be led by the country's health sector coordination committee or a similar planning committee since this GAVI support extends beyond the immunisation programme into the overall health sector.

A recent assessment of the country's health system barriers is required and must be used to justify the activities proposed in the health system strengthening proposal.

GAVI must receive audit reports within one year of the close of each financial year. These should be generated through the existing country auditing system.

3.4.3 How long does health system strengthening support last?

GAVI health system strengthening support is available for the length of the national health sector strategic plan (or country equivalent).¹⁹

Countries can reapply for GAVI health system strengthening support as often as a new national health sector plan or comprehensive multi-year plan for immunisation is developed.

If a country is mid-way through its health sector planning cycle, GAVI health system strengthening support can be provided through to the end of that cycle, but another proposal will have to be submitted to cover the next cycle. GAVI health system strengthening support is not appropriate for countries with less than a year remaining in their current planning cycles. In such cases, planning for GAVI health system strengthening support should coincide with the start of the next health sector strategic plan or comprehensive multi-year plan.

The GAVI Alliance Board has approved funding for health system strengthening support up to 2010, with a possible extension to 2015. The extension will depend on the outcome of an evaluation due to take place in 2009.

Guidelines and application forms for health system strengthening support may be downloaded from the GAVI Alliance website²⁰.

Look for:

- *Guidelines for HSS*, available in English and French.
- *Application form for HSS*, available in English and French.

¹⁹ In cases where there is a difference between the two, the proposal should be aligned with the timeframe of the broader health sector strategic plan.

²⁰ All GAVI guidelines are available at <http://www.gavialliance.org/support/how/guidelines/index.php>.

3.5 Civil society organisation support

GAVI Alliance support to strengthen the involvement of civil society organisations (CSOs) in immunisation and related health services is a new, innovative and catalytic type of support, linked to health system strengthening support. Civil society organisations have a long history of involvement in public health and community mobilisation and they are often engaged in increasing access to health and other social services for marginalised and hard-to-reach populations.

The aim of GAVI Alliance support to CSOs is to build sustainability at country level by involving local CSOs in the planning and delivery of immunisation and other health services. GAVI funding for CSOs is not designed to support the creation of new, stand-alone projects, but to encourage collaboration and coordination between CSOs and the public sector.

Proposals for civil society organisation support should be developed by the government and its health sector coordination committee, with input from the interagency coordinating committee and the CSOs. Whenever possible, countries should submit their proposals for civil society organisation support to GAVI with their health system strengthening proposals.

²¹ Guidelines for GAVI Alliance CSO support: Support to strengthen the involvement of civil society organisations in immunisation and related health services. Geneva, GAVI Alliance, 2007.

Question & answer

How does GAVI define “civil society organisation”?

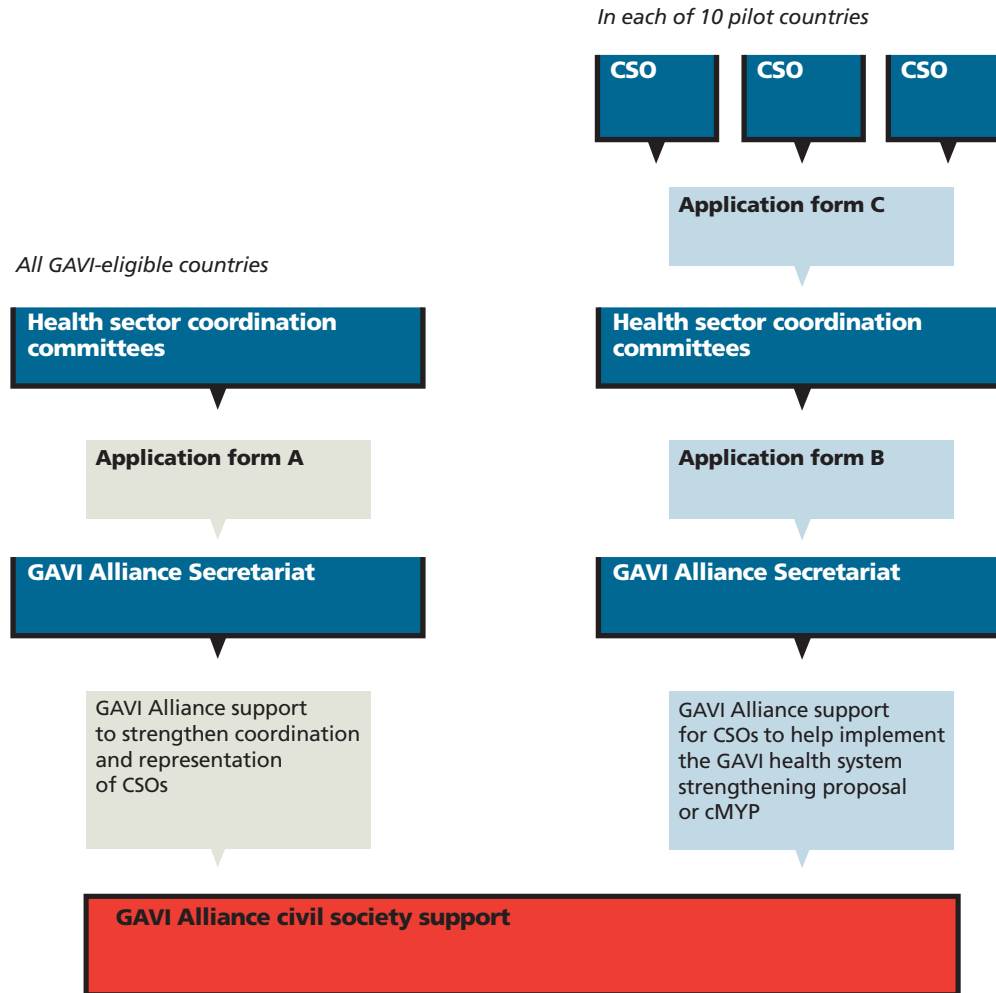
Civil society organisations can be national, local, regional, or international in structure and scope, and typically include:

- nongovernmental organisations;
- community-based groups or partnerships;
- professional associations;
- academic and technical institutions.

They must be involved in delivering, providing technical assistance to, monitoring/evaluating, mobilising communities to increase demand for, advocating/lobbying for, or conducting operational research in relation to, immunisation and other child and maternal health services and programmes.

In addition, CSOs must have aims consistent with the spirit and purposes of the GAVI Alliance and be willing to work collaboratively with governments, the GAVI Alliance Secretariat, and other GAVI Alliance partners.²¹

Figure 5 **GAVI Alliance support to civil society organisations**



3.5.1 What does the GAVI Alliance provide?

The GAVI Alliance provides two types of civil society organisation support to countries, as laid out in Figure 5:

- **Support to strengthen coordination and representation of CSOs:** This support is available to *all* GAVI-eligible countries. A lump sum of between US \$ 10,000 and US \$ 100,000 is available to strengthen coordination among, and with, CSOs involved in immunisation, child health care, and health system strengthening and to enhance civil society representation in health sector coordination and interagency coordinating committees.
- **Support for CSOs to help implement the GAVI health system strengthening proposal or comprehensive multi-year plan:** This funding is available to enable CSOs in a selected group of *10 pilot countries only* to support the implementation of, or provide technical assistance to, activities in their health system strengthening proposals and/or comprehensive multi-year plans.

**In the period, 2007–2009,
the 10 pilot countries are:²²**

Afghanistan	Georgia
Burundi	Ghana
Bolivia	Indonesia
Democratic Republic of the Congo	Mozambique
Ethiopia	Pakistan

GAVI support for CSOs is in addition, and complementary, to any other GAVI funding awarded to a country. It is integrated into the existing GAVI mechanism for health system strengthening support to encourage a harmonised, country-driven approach and avoid fragmenting support over multiple programmes. Requests for civil society organisation support should therefore, to the extent possible, be aligned with the country's proposal to GAVI for health system strengthening support. The support that each country is eligible to receive is listed in the CSO support guidelines.²³

3.5.2 What are the conditions for civil society organisation support?

The conditions for civil society organisation support are different for the two different types of funding. In the case of requests for support to strengthen coordination and representation of CSOs (available to all GAVI-eligible countries), countries must describe how they will carry out and manage a CSO mapping exercise, including the specific methodology they will use.

²² The selection criteria for these 10 pilot countries are outlined in section 4 of this Handbook.

²³ CSO support guidelines available at http://www.gavialliance.org/resources/GAVIGuidelines_CS0_24May2007.doc

The mapping should include:

- names of CSOs involved in, or contributing to, immunisation, child health care, and/or health system strengthening, plus details of their capacities, and the scope of their activities, including the target groups and nature of the activities (e.g. either delivering, technically assisting, or socially mobilising);
- location of CSO operations, number of beneficiaries, and duration of operation;
- names of CSOs currently contributing to meeting national immunisation and health goals;
- existing coordination mechanisms for CSOs and a description of how they work together;
- funding mechanisms and the flow of funds from donor and/or ministries of health to the CSOs;
- results of any other previous mapping exercises involving CSOs in the country.

In each country, this mapping exercise should result in a database of the CSOs that are contributing or might contribute to the

country's comprehensive multi-year plan for immunisation and/or its health system strengthening efforts. Results of the exercise should be an improved understanding of the competencies of the CSOs and the identification of suitably qualified CSOs that might partner government to address service delivery gaps and other health system needs. Mechanisms and support for periodically updating the database of CSOs should also be established in each country.

The proposal for civil society organisation support should include a section on the proposed process for fairly and transparently nominating CSOs to the national-level health sector coordination committee (or equivalent), and the interagency coordinating committee responsible for immunisation. There is no deadline for this application. Countries may apply any time.

The second type of support, available to 10 countries only during the period 2007–2009, is intended to strengthen partnerships between government and relevant CSOs, while also supporting CSO activities that will help the country deliver the services contemplated in its comprehensive multi-year plan and/or GAVI health system strengthening proposal.

The health sector coordination committee in each of the 10 pilot countries will encourage local CSOs that are active in child health and immunisation to submit requests for support. The CSOs will be required to provide detailed programme implementation plans, as well as budgets showing the costs to be covered through the GAVI Alliance and other partners. From among these proposals, the health sector coordination committee will evaluate and select those plans that will become part of an overall request to the GAVI Alliance for civil society organisation support.

3.5.3 How long does civil society organisation support last?

GAVI Alliance support to strengthen the involvement of CSOs in immunisation and related health services is a time-limited investment, available for two years only.

The impact and process of this initial investment to support the involvement of CSOs will be evaluated in late 2009 or 2010 to assist the GAVI Alliance and GAVI Fund Boards in deciding on possible investment options for CSOs in the future.

The application deadlines are the same as those for GAVI health system strengthening support.²⁴ Guidelines and application forms for CSO support, as well as additional reference materials, are available for downloading from the GAVI Alliance website.

Look for:

- *Guidelines and application form for CSO support*, available in English and French.²⁵
- *Q&A GAVI Alliance support for civil society organizations*, available in English and French.²⁶

²⁴ Deadlines can be found on <http://www.gavialliance.org/support/how/process/calendar/index.php>

²⁵ Blank proposal forms, with instructions, can be downloaded from the GAVI Alliance website at <http://www.gavialliance.org/support/how/guidelines/index.php>.

²⁶ This document is available at http://www.gavialliance.org/resources/CSO_Q_A_final290807.doc



4

How to apply for GAVI support

- 4.1 Proposal development 51
 - 4.1.1 HSS proposal development 52
- 4.2 Proposal submission 53



4 How to apply for GAVI support

4.1 Proposal development

Requests for GAVI support must be made by governments of eligible countries. Proposals will be developed in collaboration with each country's interagency coordination committee (ICC) and/or health sector coordination committee (HSCC), depending on the type of support requested (see below).

Proposals for types of support that require submission in coordination with interagency coordinating committees

- new vaccine support;
- injection safety support;
- immunisation services support.

Proposals for types of support that require submission in coordination with health sector coordination committees

- health system strengthening support;
- civil society organisation support.

All eligible countries (GNI/capita in 2003 less than US\$1,000) are invited to submit proposals for GAVI support. Proposals and annual progress reports must be submitted to the GAVI Secretariat by specific deadlines set for each year. These deadlines are posted on the GAVI website and are also widely disseminated via the GAVI regional working groups and the annual 'country update letter' from the GAVI Secretariat to Ministries of Health in GAVI-eligible countries.

The types of support available are new vaccine support (NVS), injection safety support (INS), immunisation services support (ISS), health system strengthening support (HSS) and civil society organisation support (CSO). These are described in detail in chapter 3 of this Handbook. The different forms of GAVI support can be applied for independently of each other, however, countries have found it beneficial to use the experience from one GAVI proposal development process for development of other types of proposals.²⁷ For example, it is quite common that there is some overlap in membership between the ICC (which handles ISS, NVS and INS proposals) and the HSCC (which handles HSS and CSO proposals), and these members bring valuable knowledge from one proposal development process to the other.

²⁷ Please see <http://www.gavialliance.org/support/how/guidelines/index.php> for guidelines and application forms for each available form of GAVI support.

Eligible countries are strongly encouraged to prepare their proposals and progress reports in collaboration with national partners. Before a proposal can be accepted by the GAVI secretariat, the GAVI partners at country level are required to ratify (with proof of signature) the proposals and progress reports, usually through an Interagency Coordination Committee (ICC, for ISS, NVS and INS) or the Health Sector Coordination Committee (HSCC, for HSS and CSO support), or its equivalent. However if there are reasons why GAVI partners cannot agree/ratify a proposal and do not want to sign the proposal, reasons for this should be made explicit within the proposal documentation and communication with the GAVI secretariat.

Support and technical assistance for proposal development is available through partners in each country.

Each GAVI proposal should be in line with the country's planning framework. For example, if a country submits an HSS proposal, approval will be given to support the country until the end of the country's current planning cycle. With a new country plan, a new proposal for GAVI support should be submitted. The same applies to other types of GAVI support. GAVI support is therefore now completely aligned with country planning cycles.

Question & answer

Does the signature of an interagency coordinating committee member on an application or a progress report signify endorsement of all the contents of the document/s?

No. The purpose of the signature is to demonstrate that partners have participated in the process of preparing the document, that they are aware of the contents, and have had an opportunity to influence the outcome.

Can a country send its proposal, progress reports, and supporting documents by electronic mail?

Yes, countries are indeed encouraged to send documents electronically, including the scanned signature pages.

4.1.1 HSS proposal development

For HSS proposal development, countries can request up to USD 50,000 through the GAVI Secretariat to help draft the HSS proposal. The HSS guidelines page 8 outline this process. Countries often use these funds to fund stakeholder consultation meetings (eg. sub national representatives or donors) at the national or sub national levels, or for consultants to help draft the proposal itself. Country ownership of the process and the proposal is important and how to evidence country ownership is outlined in the guidelines (ie. requirement for signed meeting minutes).

Request for changes in new vaccine support

If a country wishes to change to a different combination vaccine but containing the same antigens or to change the presentation of a vaccine to a different number of doses per vial after the GAVI Alliance has approved support, it must submit a request regarding the proposed change. Ideally, this request should be submitted with the annual progress report. The proposed change or changes must be justified, and the country's plan for the introduction of a new vaccine must be revised accordingly. In such cases, the introduction plan should be updated, reviewed, and endorsed by the interagency coordination committee to ensure that it addresses issues such as cold chain functioning and storage capacity, as well as plans for health worker training. A request should then be submitted to the GAVI Secretariat, which determines if the country's proposal is consistent with the previous GAVI Alliance approval. UNICEF's Supply Division will advise if and when the revised request can be accommodated with respect to available and contracted supplies. Co-financing for additional antigens will apply as described elsewhere.

4.2 Proposal submission

Each proposal should be signed by the appropriate authorities and submitted to the GAVI Secretariat with the required documents attached. Which signatures and documents that need to be submitted with which proposal is detailed in chapter 3 of the Handbook, as well as in the respective guidelines.

Following submission, proposals and countries' annual progress reports are screened by the GAVI Secretariat for eligibility and completeness. Thereafter, each proposal and report is pre-assessed by a WHO expert group which looks at consistency of information, validity of data and conformity with the comprehensive Multi-Year Plan (cMYP) and/or the health sector plan. Written feedback is provided to the Independent Review Committee (IRC) for use in considering proposals. The IRC then meets and reviews the proposals.

Approved countries are required to submit annual progress reports (APR) by the 15th of May each year.²⁸

²⁸ The current APR form is available at <http://www.gavialliance.org/support/how/guidelines/index.php>

Question & answer

If a country from the poorest group is currently receiving DTP-HepB+Hib at a co-financing level of US\$ 0.20 per dose, how much will it have to pay to receive the pneumococcal vaccine in addition to the DTP HepB+Hib vaccine?

The country would have to continue paying US\$ 0.20 per dose for the DTP-Hep B + Hib vaccine and US\$ 0.15 per dose for the pneumococcal vaccine.

Will co-financing levels for new and underused vaccines change after 2010?

GAVI will conduct an evaluation of the co-financing policy in 2009. Current co-financing levels are expected to be revised based on the outcomes of the evaluation. The eligibility criteria will also be evaluated. Depending on the outcome of the evaluation, some countries' status and co-financing requirements might change.

5

How does GAVI provide support?

- 5.1 Direct funding transfers 56
- 5.2 Vaccine and injection material 56
- 5.3 Cash in lieu of supplies 58



5. How does GAVI provide support?

After the Independent Review Committee has reviewed a proposal, its chairperson passes the Independent Review Committee's recommendation on to the GAVI Alliance Board. Once the Board has given its approval, recommendations and funding requests are forwarded to the GAVI Fund for funding determination. Once budget approvals are made by the GAVI Fund and any co-funding entity, decisions are then communicated to the country by the GAVI Secretariat.

The GAVI Board makes three types of award, each of which is described in the sections that follow:

- direct funding transfers;
- vaccine and injection materials;
- cash in lieu of supplies.

Recommendations of the Independent Review Committee

■ **Approval:** The proposal meets all the criteria and is recommended to the GAVI Alliance Board for GAVI support.

■ **Approval with clarification:** When a proposal lacks specific data that should have been included, the GAVI Alliance Board may give provisional approval and simultaneously ask the country to submit the missing data to the GAVI Secretariat (generally within one month) and to the GAVI Alliance Board. After further review and acceptance of the clarifications, the

GAVI Secretariat approves the proposal and defines the final specifications of support.

■ **Conditional approval:** When a proposal does not meet significant proposal requirements, missing data and information must be provided at the next scheduled submission date to complement the original proposal. This new information is reviewed again by the Independent Review Committee and the proposal is either recommended to the GAVI Alliance Board for funding or not. A conditional

approval remains valid for 12 months. If the country does not meet the conditions within one year of the first submission, it will be required to resubmit the entire proposal.

■ **Re-submission:** The proposal is judged to be incomplete. A full proposal should be submitted by a future scheduled submission date for review by the Independent Review Committee and consideration by the GAVI Alliance Board.

5.1 Direct funding transfers

The GAVI Fund transfers funds directly to the designated bank account following instructions that the country provides in the banking details form, which is attached to the application form.

If the bank or the bank account number changes, the country must provide the new information to the GAVI Secretariat in writing. The GAVI Secretariat will confirm receipt of the changes, also in writing, before any transfers are made to the new bank or account.

If the interagency coordination committee does not agree that the government's bank account is the best channel, it must come to an agreement with that government regarding an alternative account that fulfils GAVI's requirements for transparency, accounting standards, long-term sustainability, and empowerment of the government. Alternative arrangements may be made through a partner agency or a commercial bank.

5.2 Vaccine and injection materials

UNICEF procures vaccine products to meet national requirements once a government has submitted a vaccine shipment plan that has been agreed with UNICEF Supply Division and that is in accordance with the country's approval for GAVI support. Subject to availability, UNICEF will supply all vaccines with vaccine vial monitors. Vaccine shipments include auto-disable syringes (for injection and reconstitution) and safety boxes in quantities sufficient to administer the vaccines provided to the target population. UNICEF purchases and synchronises shipments of vaccines and syringes for the GAVI Alliance.

UNICEF procurement

For a country that chooses to procure through UNICEF, UNICEF Supply Division will follow up with the country through the UNICEF country office, following receipt of the Decision Letter from GAVI. The country will be requested to provide a shipment plan indicating quantity and month of delivery as well as consignee contact information. UNICEF will proceed with procurement activities based on the confirmed shipment plan. Variations to the agreed shipment plan are to be communicated in writing and agreed by UNICEF and the government

concerned with explanation of the causes for change. The shipment plan will be updated as needed.

For countries procuring through UNICEF, procurement of the co-financing quantities of vaccines and related injection safety materials as agreed between GAVI and the country will follow the process of a normal procurement services transaction. The country needs to complete a request form for a new request, based on which UNICEF will prepare a cost estimate. Funds should then be deposited with UNICEF based

on the cost estimate. The country needs to have a current Memorandum of Understanding (MoU) for Procurement Services in place with UNICEF prior to transferring any funds to UNICEF. Following receipt of funds and the MoU, UNICEF shall expedite the procurement activities. For further information on using UNICEF Procurement Services and the current fee structure and to access the relevant forms, please refer to the UNICEF website http://www.unicef.org/supply/index_procurement_services.html

5.3 Cash in lieu of supplies

Countries choosing to receive cash in lieu of supplies for the procurement and delivery of vaccines and associated injection safety supplies are required to:

- report through the interagency coordination committee the number and value of doses self-procured and delivered;
- record the national procurement principles and processes in its annual progress report to ensure that good procurement practices are followed (including integrity, competition, equal treatment, client service, and adherence to the GAVI Vaccine Procurement Objectives).^{29, 30}

Question & answer

Do countries always receive and continue to receive the vaccine formulations and presentations that they originally requested?

No. Vaccine formulations and presentations are subject to availability. For vaccines in limited supply, the available quantities will be allocated in accordance with the policy on prioritisation of vaccine products supplied by GAVI (see section 3.2.4). However, once a country has succeeded in introducing a vaccine product, GAVI will make every effort to assure a sustained supply.

If the supply situation changes in the time between the proposal submission and the award, what happens if a requested formulation is not available?

If a requested vaccine product (i.e. combination) is not available, countries may be eligible for additional assistance in introducing an alternative presentation.

²⁹ Documentation of the national procurement principles and process should cover the following: product range, type of tender used, invitation list and criteria for invitation, tender duration, evaluation criteria, and outcome of the procurement process.

³⁰ The GAVI Vaccine Procurement Objectives were endorsed by the GAVI Board in April 2005.

6

What are GAVI's monitoring and evaluation requirements?

6.1

Annual progress reporting 63

6.1.1 Objectives 63

6.1.2 Preparation and submission 64

6.1.3 Outcome 65

6.2

Data quality audit 65

6.2.1 Objectives 66

6.2.2 Methodology 66

6.2.3 Outcome 67

6.3

Vaccine management
assessment 68



6 What are GAVI's monitoring and evaluation requirements?

GAVI support is subject to strict performance monitoring that is designed to track progress achieved in the previous year, to declare planned targets for the following year, and to verify the sustainability of existing financing mechanisms.

There are three main activities that make up the GAVI monitoring process, each of which is described in the sections that follow:

- annual progress reporting;
- data quality auditing;
- vaccine management assessment.

6.1 Annual progress reporting

6.1.1 Objectives

The annual progress report³¹ is intended to be beneficial both to the government and the external partners of GAVI. It is submitted annually together with the WHO/UNICEF Joint Reporting Form³².

The Joint Reporting Form, which is an annual global monitoring requirement of WHO and UNICEF, provides a measure of progress against a set of standard performance and quality indicators. Together, the annual progress report and the Joint Reporting Form provide a comprehensive picture of progress over time, attainment of annual targets, and related requests for further GAVI support.

The annual progress report is designed to provide detailed information on:

- achievements in relation to targets during the previous calendar year;
- receipt and use of GAVI funds received in the previous calendar year;
- problems or constraints faced while utilising GAVI support;
- status and sustainability of financing mechanisms;

³¹ For further information, go to <http://www.gavialliance.org/support/how/guidelines/index.php>.

³² For further information go to http://www.who.int/immunization_monitoring/routine/joint_reporting/en/index.html.

- requests for new and underused vaccines for the forthcoming year, taking into account remaining stocks in the country;
- progress against stated objectives since submission of the previous annual progress report.

6.1.2 Preparation and submission

An important role of the interagency coordination committee is to assist the government in the preparation of its annual progress report to the GAVI Alliance. The regional working group may also assist in this process and should review the report before it is finalised to obtain feedback from partners at the regional level. In preparing their annual progress report, countries should:

- use standard indicators of progress from the Joint Reporting Form and/or introduce additional indicators to display trends in the evolution of immunisation programmes, either in the form of time-series tables or as graphics;
- update the standard tables on immunisation expenditures and financing, as well as the co-financing table;
- update their targets, considering previous achievements and future objectives;
- use the new coverage figures provided through the Joint Reporting Form;
- provide data related to immunisation achievements (e.g. the number of children reported as having been immunised during the previous year and targets for future years).

Once the annual progress report has been finalised with the inputs of the regional working group and in-country partners, it should be signed by the government and other members of the interagency coordination committee. This signifies the involvement of the external partners in the monitoring and reporting process. The government should ensure that the annual progress report and the necessary supporting documents reach the GAVI Secretariat by the specified closing date. Electronic copies of the report may be sent, but a hard copy, bearing the appropriate signatures, should be sent separately.

Question & answer

How should the annual progress report handle changes in plans?

The report should explain and justify any changes in plans. Changes that will result in modifications to the outcome of planned activities (for example, cold chain capacity, methods used for administering vaccines, or public knowledge of vaccination practices) should be presented with an analysis of their operational implications. The minutes of the interagency coordination committee meeting endorsing any changes to the operational plan should be attached to the annual progress report.

6.1.3 Outcome

The Independent Review Committee reviews each annual progress report, making technical comments and suggestions, and recommends one of the following three outcomes to the GAVI Alliance Board:

- continue providing support;
- request clarifications before continuing to provide support;
- request the country to resubmit its report as insufficient information has been provided.

Question & answer

Can failure to submit an annual progress report on time affect the flow of support?

Yes. All awards of support are only made on receipt of a satisfactory annual progress report. Failure to submit this report on time may result in the delay or interruption of funding support. The supply of vaccines and injection equipment, however, will not be affected.

6.2 Data quality audit

GAVI requires that countries receiving its immunisation services support conduct a data quality audit (DQA) during the second year of GAVI support. The government is responsible for setting a date for the DQA, and an external audit team should be engaged to review records and reports from a specified number of locations at the district and national level of the system, according to the standard WHO procedure for data quality audits. The costs of conducting the DQA are covered by the GAVI Alliance Secretariat.

For countries that are reapplying for immunisation services support, a repeat DQA will be required one year after approval or four years after the last successful DQA. The documents, *How to prepare for a Data Quality Audit*³³ and *The immunization data quality (DQA) procedure*³⁴ provide additional information.

³³ More information on data quality audits available at <http://www.gavialliance.org/resources/DQABriefPaper02.pdf>

³⁴ More information on how to implement a data quality audit available at http://www.gavialliance.org/resources/DQA_manual_2.pdf

6.2.1 Objectives

GAVI requires verification of the administrative reporting system by an external team for two reasons:

- to ensure that the quality (accuracy and completeness) of the administrative reporting system is sufficiently high to enable managers at all levels to detect real rises or falls in the performance of the immunisation services for which they are responsible;
- to supply GAVI with sufficiently reliable data on the number of children immunised to enable it to provide immunisation services support on a per-capita basis.

6.2.2 Methodology

During its visit to conduct the DQA, the audit team is required to report on immunisation practices at the national level and also in a sample of four districts and six health units in each district (24 health units in all). Two external auditors selected by GAVI work with two internal auditors selected by the government to conduct the audit. The team checks:

- the accuracy of recording of the number of immunisations (for the audit year);
- the transcription and aggregation of these numbers;
- reporting practices from level-to-level within in the system.

This involves a thorough analysis of recording and reporting practices at national, district, and health unit level. For example, the auditors should:

- recount data from tally sheets or registers at the health unit level;
- observe immunisation sessions taking place;
- retrieve monthly reports at all levels and compare values;
- analyse graphs and tabulations for accuracy;
- check vaccine and syringe stock ledgers for completeness.

To minimise errors by the audit team, each auditor should maintain a logbook, and collect and enter all their data into a laptop computer on a daily basis. National, district, and health unit summary sheets can then be computer-generated and key indicators of immunisation performance readily calculated, providing an immediate and valuable form of feedback for staff at each reporting level.

The audit team should submit its report to GAVI and the country's interagency coordination committee.

A data quality self-assessment protocol³⁵ is available to assist countries in assessing their own routine reporting system in advance of the external data quality audit.

³⁵ The immunization data quality self-assessment (DQS) tool. Geneva, World Health Organization, 2004, is available at http://www.who.int/immunization/documents/WHO_IVB_05.04/en/index.html.

6.2.3 Outcome

In addition to observations and recommendations for improvement, the data quality audit (DQA) report contains two key components:

- a composite index measuring the quality of the reporting system;
- a “verification factor”, which is calculated on the basis of the divergence between recounted records and existing aggregate reports. This factor (the ratio of recounted DTP₃ to reported DTP₃) should be equal to, or greater than, 0.80 (80%).

If the verification factor is equal or greater than 0.8 (80%), the reporting system is considered to be of satisfactory quality and execution of subsequent DQAs may be requested by GAVI after longer intervals of time.

If the verification factor is lower than 0.8 (80%), the country has two options – it may arrange to repeat the DQA in the second year or it may choose to conduct a coverage survey, according to standard WHO cluster survey methodology, to validate the number of DTP₃ doses it has reported.

Until the DQA result is satisfactory, or exceptionally until the country has demonstrated by a coverage survey an increase in the number of infants immunised from the previous year, GAVI will not award the ‘reward’ element of its

immunisation services support. To qualify for immunisation services support rewards in subsequent years, countries achieving low verification factors in their first DQA must repeat and earn a verification factor equal to or greater than 0.8 (80%) in a future DQA.

A country with a low DQA verification factor should prepare a plan to improve its routine reporting system (based on the DQA findings and recommendations) and then seek the endorsement of its interagency coordination committee in implementing that plan. The regional working group should be available to assist the country in formulating such a plan.

A country may conduct a data quality self-assessment (DQS) to check on the quality of its administrative reporting system. This is a useful managerial exercise either in advance of, or following the, DQA. However, GAVI neither requires nor recognises the DQS as an alternative to the DQA.

6.3 Vaccine management assessment

A country receiving GAVI Alliance support for the introduction of a new or underused vaccine must conduct an assessment of its vaccine management practices in the second year of vaccine support. It is recommended that countries conduct the assessment using the WHO/UNICEF Effective Vaccine Store Management Tool³⁶.

Alternatively, countries may choose to conduct a more thorough assessment down to service delivery level using the WHO Vaccine Management Assessment Tool.³⁷ Assessments should be repeated every three to five years.

³⁶ WHO/UNICEF Effective Vaccine Store Management Tool. Geneva, World Health Organization, 2004 (document WHO/IVB/04.16-20; available at http://www.who.int/vaccines-documents/DocsPDF05/IVB_04_16-20.pdf).

³⁷ WHO Vaccine Management Assessment Tool. Geneva, World Health Organization, 2005 (document WHO/IVB/05.02; available at http://www.who.int/vaccines-documents/DocsPDF05/796_Final_version.pdf).

Annexes

Annex 1

**Documents required
with proposals** 71

Annex 2

**Calculating ISS investment and
reward payments** 75

Annex 3

List of URLs 77

Annex 4

Contact information 80



Annex 1

Documents required with proposals

These documents are accepted by GAVI in either English or French: other languages will need to be translated before the document is submitted.

1.1 Comprehensive multi-year plan

A comprehensive multi-year plan for immunisation:

- Provides national goals, objectives, and strategies for three to five years based upon a situational analysis;
- Addresses all components of the immunisation system relevant to the country;

- Creates synergies between various immunisation initiatives – polio, measles, maternal and neonatal tetanus (MNT), injection safety, etc.
 - to avoid the need for separate plans;
- Integrates in one plan those activities common to accelerated disease control and other initiatives and routine immunisation, to avoid duplication;
- Includes costing and financing assessments to be linked to the relevant planning cycle;
- Encourages links with other programmes as recommended by Global Immunisation Vision and Strategy (GIVS); and
- Includes scenarios and strategies for financial sustainability.
- Reference:

WHO-UNICEF guidelines for developing a comprehensive multi-year plan (cMYP), WHO Immunization, Vaccines and Biologicals and UNICEF, 2005.³⁸

Immunization Costing and Financing: A Tool and User Guide for comprehensive Multi-Year Planning, WHO Immunization, Vaccines and Biologicals and UNICEF, 2005.³⁹

1.2 National action plan for injection safety

The national plan for injection safety, ideally a part of the comprehensive multi-year plan, should at a minimum describe activities that address the following issues:

- Ensuring compliance with the WHO/UNICEF/UNFPA statement of 1999⁴⁰ both now and after the resources provided by GAVI are no longer available;
- Providing the training and supporting the necessary behaviour change among health care providers;
- Providing information, education and communication to health care workers on the risks resulting from unsafe injections and poor sharps waste management;

³⁸ <http://www.who.int/vaccines-documents/DocsPDF06/832.pdf/>

³⁹ User's Guide <http://www.who.int/vaccines-documents/DocsPDF07/848.pdf/> Excel spreadsheet http://www.who.int/immunization_financing/tools/cmyp/en/

⁴⁰ Safety of injection, WHO-UNICEF-UNFPA joint statement on the use of AD syringes in immunisation services, WHO/V&B/99.25.

- Monitoring programme progress (including specific indicators that will be used and annual targets for these indicators);
- Improving the safety of the disposal of medical waste (especially sharps) resulting from immunisation activities. This will require the formulation of policy, assessment of the waste management system, and the selection of appropriate waste disposal systems for all levels of health care facilities.
- Reference:
*A reference outline for developing a National Policy and Plan of Action for injection safety in national immunisation programmes, Immunisation Safety Priority Project, Vaccine Assessment and Monitoring, World Health Organization, Geneva, 2003.*⁴¹

1.3 Plan for the introduction of new vaccines

A country plan for the introduction of a new or underused vaccine (ideally part of the comprehensive multi-year plan for immunisation) should include:

- A summary of the comprehensive multi-year plan referring to the introduction of new and underused vaccines;
 - A summary of cold chain capacity and readiness to accommodate new vaccines, stating how the cold chain expansion (if required) will be financed and when it will be in place;
 - How financial sustainability and co-financing will be achieved (for the comprehensive multi-year plan and beyond);
 - Burden of relevant diseases (based on reported cases), using the comprehensive multi-year plan data (if available);
- Lessons learned from the introduction of previous new and underused vaccines in the country;
 - List of the vaccines to be introduced with support from GAVI (and presentation); and
 - Using the tables in Annex 2 (and the comprehensive multi-year plan), data for the first preference vaccine on the:
 - b Specifications of vaccinations with the new vaccine;
 - c Portion of supply to be procured by the country; and
 - d Portion of supply to be procured by GAVI.
 - Reference:
*Vaccine Introduction Guidelines, Adding a vaccine to a national immunization programme: decision and implementation, (WHO/IIVB/05.18), WHO/Geneva, 2005*⁴²

⁴¹ http://www.who.int/immunization_safety/publications/safe_injections/en/outline_national_policy_injection_safety_E.pdf

⁴² <http://www.who.int/vaccines-documents/DocsPDF05/777-screen.pdf>

Annex 2

Calculating ISS investment and reward payments

Example – Investment calculation

400,000	Children <1 year of age targeted to receive DTP ₃ in the first year following GAVI approval of the country's proposal
– 380,000	Children <1 year of age who received DTP ₃ vaccine the year <i>before</i> GAVI approval of the country's ISS proposal (initial baseline)
= 20,000	Additional children < 1 year of age who received DTP ₃ in the first year following GAVI approval (performance indicator)
x US\$ 20	For every additional child
= US\$ 400,000	Total investment , disbursed in year of approval (25%), year 1 (25%), and year 2 (50%)

Example – Reward calculation

(based on achievement in second year of award)

440,000	Children <1 year of age who received DTP ₃ in the second year of GAVI support
– 400,000	Children <1 year of age targeted to receive DTP ₃ in the first year following GAVI approval of the country's proposal (baseline)
= 40,000	Additional children < 1 year of age who received DTP ₃ in the second year following GAVI approval (performance indicator)
x US\$ 20	For every additional child
= US\$ 800,000	Total reward , disbursed by GAVI in third year

Example – Reward calculation

(based on achievement in third year of award)

435,000	Children <1 year of age who received DTP ₃ in the third year of GAVI support
– 440,000	Children <1 year of age who received DTP ₃ in the preceding year (second year) or the highest coverage year since the ISS award. (baseline)
= – 5,000	Additional children < 1 year of age who received DTP ₃ in the second year following GAVI approval (performance indicator)
x US\$ 20	For every additional child, but no additional children immunised, so no rewards paid
= US\$ 0	Total reward , disbursed by GAVI in fourth year after first ISS award

Annex 3

List of URLs

GAVI Alliance home page

<http://www.gavialliance.org>

**GAVI guidelines and forms
(proposal, data quality audit, progress report)**

All of the following guidelines and application forms can be downloaded from the GAVI website
<http://www.gavialliance.org/support/how/guidelines/index.php>

For **immunisation services support** (ISS), **injection safety support** (INS) and new and under-used vaccine (NVS) (Revised July 2007)

- Guidelines for ISS, INS, and NVS, available in English, French and Russian
- Application form for ISS, INS and NVS, available in English, French, and Russian
- Calculation of required NVS support, excluding rota and pneumo vaccines, available in English, French, and Russian
- Calculation of required NVS support – Rota and Pneumo vaccines, available in English, French, and Russian
- Guidelines for prioritisation of vaccine products supplied by GAVI, available in English and French (February 2007)

For support to **health system strengthening** (HSS) (Revised March 2007)

- Guidelines for HSS, available in English and French
- Application form for HSS, available in English and French

For support to **civil society organisations** (CSO) (Revised May 2007)

- Guidelines and application form for CSO support, available in English and French

Country **annual progress reports** (Revised April 2007)

- Country Annual Progress Report form, available in English and French
- Country Annual Progress Report Vaccine Request form, available in English and French

Data quality audit

- DQA Briefing paper, available in English and French
- DQA Annexes (July 2003)
- DQA Manual, available in English (January 2004)
- DQA Worksheet, available in English (July 2003)
- DQA Evaluation (WHO) available in English (July 2005)

Deadlines

- GAVI proposal review calendar
<http://www.gavialliance.org/support/how/process/calendar/index.php>

Comprehensive multi-year planning

- WHO-UNICEF guidelines for developing a comprehensive multi-year plan
<http://www.who.int/vaccines-documents/DocsPDF06/832.pdf>
- Immunization Costing and Financing: A Tool and User Guide for comprehensive Multi-Year Planning (cMYP)
<http://www.who.int/vaccines-documents/DocsPDF07/848.pdf>
- cMYP costing and financing tools, including Excel spreadsheet also downloadable
http://www.who.int/immunization_financing/tools/cmyp/en/

Financial sustainability

- Guidelines for preparing a financial sustainability plan (FSP) for a national immunisation programme available in English, French, Portuguese and Russian
http://www.who.int/immunization_financing/tools/en/
- Financial sustainability diagnostic tool for a national immunisation programme, available in English and French
http://www.who.int/immunization_financing/tools/en/

Injection safety

- National policy and plan of action for injection safety in immunisation programmes
http://www.who.int/immunization_safety/publications/safe_injections/en/outline_national_policy_injection_safety_E.pdf
- Safety of injections, WHO-UNICEF-UNFPA. Joint statement on the use of auto-disable syringes in immunisation services (WHO/V&B/99.25)
<http://www.who.int/vaccines-documents/DocsPDF99/www9948.pdf>

National regulatory authority

- More information and links to guidance documentation:
http://www.who.int/immunization_standards/vaccine_regulation/en/

Vaccine introduction

- WHO vaccine introduction guidelines
<http://www.who.int/vaccines-documents/DocsPDF05/777-screen.pdf>
- Estimating the potential cost-effectiveness of using Haemophilus influenzae type b vaccine
<http://www.who.int/vaccines-documents/DocsPDF01/www654.pdf>
- Guidelines for estimating costs of introducing new vaccines into the national immunisation system
<http://www.who.int/vaccines-documents/DocsPDF02/www665.pdf>
- WHO vaccine calculator to estimate the additional space required in the cold chain when a new vaccine is introduced
http://www.who.int/immunization_delivery/new_vaccines/20.vaccine%20calculator_20july_2004.pdf

Vaccine management assessment

- WHO-UNICEF Effective Vaccine Store Management Initiative
http://www.who.int/vaccines-documents/DocsPDF05/IVB_04_16-20.pdf
- WHO vaccine assessment (tools and guidelines)
http://www.who.int/vaccines-documents/DocsPDF05/796_Final_version.pdf

Waste management

- Health care waste management tool
http://www.who.int/injection_safety/toolbox/en/Healthcarewastemanagementtool.xls

Annex4 GAVI Secretariat contact information

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