

## **Terms of Reference and mandate for the 2009 GAVI Alliance integrated new proposals Independent Review Committee (IRC)**

### **1. Background:**

Since its creation, the structure and composition of GAVI's Independent Review Committee for new proposals has been widely replicated by other partnerships and organisations. GAVI's IRC model has been successful thanks to three characteristics:

- 1) The committee relies upon a **wide range of experts** in public health, epidemiology, development, and economics. This means that every proposal and report is tested against a number of differing, yet equally important perspectives.
- 2) The committee is based on a **system of peer review**. Not only are IRC members experts in a variety of fields related to immunisation and health systems, they also have practical experience working in or with developing country governments.
- 3) The committee is **independent**. It makes its recommendations in an environment free from political considerations.

The current context for the review of new proposals is detailed in section 7. These Terms of Reference and mandate for the integrated Independent review Committee who will review new proposals expand on the principles, procedures and application guidelines outlined in the application guidelines and application form ([www.gavialliance.org](http://www.gavialliance.org)).

### **2. Accountability:**

The integrated new proposals Independent Review Committee (IRC) communicates its recommendations directly to the GAVI Alliance Executive Committee, which is accountable to the GAVI Alliance Board. The GAVI Alliance Board will make the ultimate decision on whether to approve funding of any new country proposals. The GAVI Alliance Board also has the responsibility for communicating its decision to countries, via the GAVI Secretariat.

### **3. Mandate:**

The integrated proposals IRC will review new proposals in accordance with policies laid down by the GAVI Alliance Board and following the criteria for eligibility and assessment laid out in the application guidelines. The mandate of the integrated new proposals IRC is to review each new proposal submitted and make recommendations to the GAVI Alliance Executive Committee. This review should consider the information available to countries within current guidelines and application forms and ensure that any new proposal contributes to achieving:

- a) The GAVI Alliance's mission: 'Saving children's lives and protecting people's health by increasing access to immunisation in poor countries' and
- b) the GAVI strategic goals:
  - Contribute to strengthening the capacity of the health system to deliver immunisation and other health services in a sustainable manner;
  - Accelerate the uptake and use of underused and new vaccines and associated technologies and improve vaccine supply security;
  - Increase the predictability and sustainability of long-term financing for national immunisation programmes;

- Increase and assess the added value of GAVI as a public private global health partnership through improved efficiency, increased advocacy and continued innovation
- c) Eligibility criteria as per GAVI guidelines for eligibility of country application of support. Although this will in fact be done by the Secretariat and the pre review process, it will involve:

<i>Overall eligibility</i>			
Only national governments can apply Country has to be GAVI-eligible i.e.: GNI per capita in 2003 equal to or less than US\$ 1,000			
<i>General assessment criteria for approval of country proposals for support</i>			
1. Well functioning Inter-agency Co-ordination Committee (ICC) or Health Systems Co-ordination Committee (HSCC)			
2. Application submitted by Ministry of Health, and endorsed by Ministry of Finance and the relevant national coordination body (ICC or HSCC)			
3. Evidence that the proposed support from GAVI is fully synchronised with national planning and budgeting processes			
4. A comprehensive Multi-year Plan for Immunisation, synchronised with Health Sector Strategic Plan, including: <ul style="list-style-type: none"> <li>• A situation analysis of the immunisation programme</li> <li>• Rigorous analyses of the current and future costing and financing of the programme</li> <li>• A plan to reduce vaccine wastage and drop-out rate, and a strategy for improving immunisation safety</li> </ul>			
5. A satisfactory report on the utilisation of GAVI support in the Annual Progress Report (a condition for continuation of support)			
<i>Specific assessment criteria for approval of country proposals for support</i>			
<b>Immunisation Services</b>	<b>Injection Safety</b>	<b>New and Underused Vaccines</b>	<b>Health Systems Support</b>
6. Annual targets for increasing number of infants (0-11 months) to receive DTP3 7. A plan to increase access to immunisation (as part of the comprehensive Multi Year Plan (cMYP))	6. GAVI Approval for another type of support 7. Action plan for safe injections and safe management of sharps	6. National DTP3 coverage over 50% (except for Yellow Fever vaccine) 7. Agreed co-financing of the vaccine by Government from the on-set of support 8. Agreement to undertake regular Vaccine Management Assessments 9. Plan and budget for the introduction of the new vaccine (within cMYP) 10. Reasons for new vaccines introduction 11. Preparatory activities and budget for new vaccines introduction	Described in section 6.2 b below

- d) and specifically respond to the following criteria for introduction of new vaccines:  
**Yellow Fever vaccine:** GAVI will contribute to topping-up existing government financial commitments for yellow fever vaccine, where it is already part of a routine immunisation programme, and where yellow fever coverage is lower than measles coverage.

***Measles vaccine:*** GAVI will provide support for countries to introduce second dose measles vaccination into their routine immunisation programme, if this is included in the country's cMYP.

***Hepatitis B, Hib and pneumococcal vaccines:*** Any country with DTP3 coverage above 50% will be considered for Hepatitis B, Hib and pneumococcal vaccine support if these vaccines are not currently part of their routine immunisation programme. Support is for immunisation of infants under one year of age. In the year of introduction of pneumococcal vaccine countries could get additional support of pneumococcal vaccine for catch-up campaigns of children of 12-23 months. ***Rotavirus (in the Americas and Europe):*** Any GAVI-eligible country in these regions with DTP3 coverage above 50% will be considered for rotavirus vaccine support for their routine immunisation programme. New applications for rotavirus vaccine support are accepted for the oral vaccine in a 2 or 3-dose schedule. Support is for immunisation of infants up to 6 months of age for completion of the course (according to manufacturers' current recommendations).

#### **4. Terms of Reference:**

The integrated new proposals IRC will undertake the following tasks:

1. Review country proposals and all other relevant documentation attached to the proposal, such as Health Sector Plans, costed immunisation comprehensive Multi Year Plans (cMYPs), Mid Term Expenditure Frameworks (MTEFs), WHO/UNICEF Joint reporting Forms (JRFs); Financial Management Assessments.
2. Provide the GAVI Secretariat with final evaluation reports and recommendations of support for each country reviewed;
3. Provide the GAVI Secretariat with a consolidated report of the review which should include recommendations for improving funding, application, review and monitoring processes.
4. The IRC chair, in addition, is expected to :
  - 4.1 facilitate consensus amongst different reviewers on the recommendations for each country application
  - 4.2 Provide a consolidated report of the review to the GAVI Alliance Executive Committee

#### **5. IRC Membership:**

IRC members generally serve for a term of 3 years. It is proposed that the integrated new proposals IRC will have 14 members and a chair. When new members are needed, GAVI issues a call for nominations to its partners, specifying the particular area of expertise and qualifications needed. Once nominations are submitted, the pool of experts and proposed chair is submitted to the Programme and Policy Committee for review and to the executive committee of the board for approval. The Chief Executive of the GAVI Alliance will then select members from approved pool of members (Annex 2). IRC members receive an honorarium for their contribution to each review.

The increasing complexity of new proposals submitted to the GAVI Secretariat requires an IRC with a broad range of expertise to cope with new policies in areas including:

- Immunisation programme planning
- Epidemiology and disease control of vaccine preventable diseases
- Health system planning and health financing
- Health service delivery, including at the community level
- Demand generation strategies
- Reproductive and child health services

- Human resource Management
- Logistics and procurement
- Auditing and financing

Broad expertise in these various health disciplines is necessary, but not sufficient. Practical, “system-wise” experience in low- and middle-income countries and integrity are also a prerequisite. Due regard shall be paid to the importance of selecting experts on as wide a geographic basis as possible. Primarily, these experts should be selected from low and middle income countries.

Each IRC member will be asked to sign a confidentiality and conflict of interest statement (annex 3). Specifically, IRC members will not come from Alliance partner agencies, not have taken part in technically assisting country applications of countries they are reviewing and not have taken part in the pre-review processes.

Lessons learned from the 2009 integrated proposals IRC will be used for future reviews.

## **6. IRC modus operandi:**

**6.1 Dates and duration:** Both 2009 integrated new proposal reviews will be conducted as desk exercises in Geneva; the first from 1<sup>st</sup> – 12<sup>th</sup> June and the second from 19<sup>th</sup> – 30<sup>th</sup> October. Each review will include a one day briefing and one debriefing day. The actual duration of the IRC may decrease if the numbers of proposals submitted is significantly fewer than expected.

**6.2 Mechanism for review and recommendation:** An average of 3 new proposals will be reviewed per day. New proposal IRC members will read each new proposal, and select two to three members to review it in-depth. All proposals are checked for endorsement by the national Ministers of Finance and Health. Countries must also show evidence that the proposal development was an inclusive process with the involvement of relevant stakeholders. If members have a conflict of interest stemming from their work in any particular country, they state it at the outset of the review and excuse themselves from any discussions based on the relevant country proposal. Once each proposal/report has been reviewed in detail, the IRC members responsible provide a presentation on its content to the rest of the team. Final recommendations are made during the team’s deliberation, which rests with consensus on the overall merits of each proposal.

At the end of each review, the IRC will provide one detailed report for each proposal and one overall report for the Executive Committee. The overall report will include recommendations for improving the IRC review and country application processes. The IRC makes one of four possible recommendations for each proposal. These recommendations are summarised below:

<b>Recommendations</b>	<b>Definition</b>
<b><i>Approval:</i></b>	The application meets all the criteria and is approved for GAVI support
<b><i>Approval with clarification:</i></b>	The application lacks specific pieces of data, which must be provided (generally) within a month. The requested data must be received before the application is considered officially approved for GAVI support, but the proposal does not need to be reviewed again by the IRC.
<b><i>Conditional approval:</i></b>	The application does not fulfil specific or significant application requirements. Missing requirements must be provided in a subsequent proposal review round to complement the original application. Conditional approvals will be valid for 12 months. If the conditions are not met within one year of the first submission, re-submission of a new application is required.
<b><i>Resubmission:</i></b>	The application is incomplete and a full application should be submitted in a subsequent proposal review round.

#### **a. Support for the IRC decision making process**

In addition to logistics support from GAVI Secretariat staff, the IRC is assisted when necessary by Alliance partner staff, who may be requested for points of clarification. The IRC will also receive a pre-assessment report, an assessment guide and all supporting documents submitted with proposals.

#### **b. Proposal specific issues**

***Health Systems Support (HSS):*** The review of HSS proposals should determine whether each proposal adds value to existing efforts in the health sector to improve and sustain high immunisation coverage rates and to contribute to a country's achievement of MDG 4. For each proposal, the IRC focuses on the following questions:

- a) Has the proposal been developed through an inclusive process with various stakeholders<sup>1</sup>?
- b) Has the proposal been aligned with current trends in the country's health sector development process<sup>2</sup> (e.g. health system policies, plans, and management structures)?
- c) Does the proposal identify priority problems in the health sector that impede achievement of immunisation and other child health outcomes?
- d) Do the proposed interventions adequately address the problems?
- e) Can this proposal be implemented<sup>3</sup>?
- f) Is the financing plan robust and adequately aligned with health system financing?
- g) Does the proposal adequately address how progress will be monitored and flow of funds tracked?
- h) Is the proposed HSS / CSO support sustainable?

<sup>1</sup> Elaborated through a systematic, inclusive and verifiable dialogue with all major health sector partners, including civil society.

<sup>2</sup> Outlined in such documents as the country's PRSP; Sector Policy or Health Sector Plan; SWAp joint programme of work; Medium Term Expenditure Framework; UN Common Country Assessments (CCA) and United Nations Development Assistance Framework (UNDAF) or Budget Framework Papers

<sup>3</sup> By outlining a realistic balance of inputs (including technical) for the expected outcomes, is of sound technical quality and identifies annual progress milestones and SMART process and impact indicators in relation to set objectives.

- i) Does the proposal clearly appraise the risks of this investment, as well as the potential mitigating factors
- j) Overall, does the proposal make a compelling case for investment?

The IRC should also confirm that:

- The proposal has been elaborated through an inclusive process;
- Proposals meet the basic conditions for application (as listed in guidelines);
- Proposals address constraints identified as priorities in the national health sector plan and those activities are elements of broader, more comprehensive national plans.
- Activities are justified as critical for raising and / or sustaining immunisation coverage.
- The level and nature of GAVI support is likely to make a difference.
- Progress can be monitored; that there are adequate monitoring and reporting arrangements and validate any country specific monitoring indicators.
- The proposal is approved by the Ministry of Health, the Ministry of Finance and endorsed by the key in-country development partners.

***New Vaccines Support (NVS):*** The IRC review of new vaccine proposals evaluates:

- If the specific vaccine introduction is epidemiologically justified. This decision primarily relies upon the recommendations of the Strategic Advisory Group of Experts (SAGE).
- If the country's request for support for introduction of a new vaccine matches with the country programme for routine immunisation of infants of the cMYP and with the framework for country planning and budgeting for EPI.
- Whether the country proposal provides a thorough analysis of programmatic issues relative to the introduction of the new vaccine like cold-chain and logistics capacity, and readiness to accommodate the new vaccine.
- Whether the country's cMYP includes the financial analysis relative to the planned introduction of the new vaccine identifying the financial gap and the strategies to address that gap.

***Immunisation Services Support (ISS):*** The IRC review of immunisation services support evaluates:<sup>4</sup>

- If proposed future targets for children to be reached with DTP3 are realistic.
- How estimated ISS awards are factored into cMYP activities and budgets.

***Civil Society Organisation type B support (CSO):*** GAVI currently offers two types of support for CSOs Type A and B. Type A funds are small lumps-sum funds (min 10,000 – max 100,000 US\$) for all GAVI eligible countries for strengthening coordination of CSOs at national levels and proposals are reviewed by the CSO task team. Type B funds are only available to 10 pilot countries to implement HSS and/or cMYPs.

The review of CSO type B proposals determines whether each proposal adds value to existing efforts in the health sector to improve and sustain high immunisation coverage rates through support of the cMYP or the GAVI HSS proposal. For each proposal, the IRC evaluates:

- If the proposal is aligned with the country's health system policies, plans, and management structures.

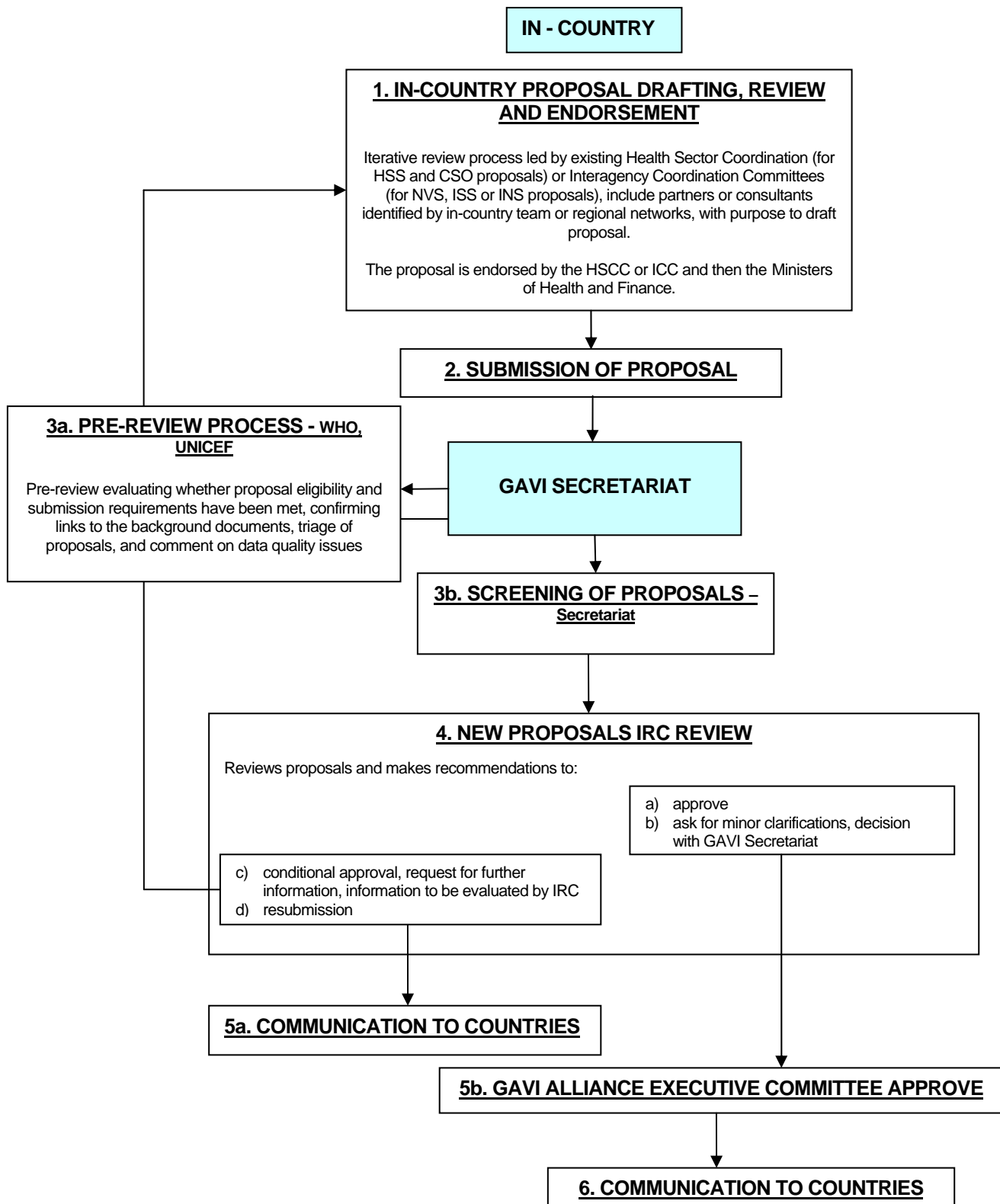
---

<sup>4</sup> Note that the ISS program is currently under review.

- If the proposal identifies key gaps that impede delivery of immunisation and other health services.
- Whether the proposed solutions will effectively address health systems gaps.
- If the proposed solutions can be implemented with the time/funding available.
- Whether budgets are robust and well sourced (e.g. are unit prices and other cost assumptions included)
- How the country will monitor progress and track funding flows.
- Whether the country can sustain progress once GAVI CSO support phases out.
- The risks of the investment, as well as the potential mitigating factors

***Injection Safety Support (INS):*** The IRC review of Injection Safety Support evaluates the country needs for safe injection equipment in the delivery of routine immunisation programme, as indicated by the cMYP and by the country policy and strategy for Injection Safety.

7. Overall context for the proposal review process:



## 7.1 In-country review:

All major in-country partners are expected to participate in the formal review of the proposal. This should include a pre-screening for accuracy and consistency by in-country partners. This in-country review process should ensure that several criteria have been met:

- the proposal and its objectives are relevant to the health (or immunisation) systems problems of the country;
- likely to result in health system improvement;
- that is likely to be instrumental in achieving sustained performance of the immunisation program;
- the proposal is supported by a technically sound situation analysis sections of various policy documents, reviews and study reports; the HSS proposal is complementary to what partners are already doing or planning to do in strengthening the health system and the immunisation programme
- the proposal is likely to achieve its stated objectives by articulating an adequate strategy, realistic balance of inputs for the expected outcomes and is of sound technical quality;
- the proposal has been elaborated through a systematic and inclusive process involving but not limited to dialogue with partners on the sector;.

Once the review is complete, the proposal is signed by the members of the Health Sector Coordinating Committee (HSCC) or Interagency Coordinating Committee (ICC) and then the Ministers of Health and Finance.

## 7.2 Submission of proposal

A partner-endorsed proposal from the MOH, with supporting documentation, is submitted to the GAVI Secretariat by the deadline to ensure the timeliness of subsequent review processes. The GAVI Secretariat then screens proposals for eligibility and possible missing information. The GAVI Secretariat will ensure that:

- the minimum set of documents required are available
- the minimum set of requirements such as government signatures for a new proposal have been met

## 7.3 Pre-review of new proposals at global level

There will be two pre-review teams; one for HSS and CSO proposals, coordinated by WHO HSS team and one for NVS / ISS and INS proposals, coordinated by WHO IVB team and by UNICEF Supply Division. These pre-review reports support the IRC's recommendation making process in several ways, but mainly by increasing the efficiency of the IRC's time.

The pre-review team will ensure that

- Targets for new vaccines and ISS are realistic and aligned with reported figures on the WHO/ UNICEF Joint Reporting Format (JRF)
- there is consistency between figures quoted in text and tables, and between figures in the applications and those in other supporting documentation
- there is a summary of key background and supporting documents that are referenced in the new proposal for easy reference

- the proposed activities are in line with recommendations from major reviews of the health sector and the immunisation program.

It is not the pre-review team's mandate to assess the quality of the proposal or pass judgment on any of the proposed strategies or activities; rather, its aim is to ensure that the time of the IRC is spent most judiciously in assessing the merits of each proposal.

#### **7.4 New proposals Independent Review Committee**

See previous sections 1-6 for details.

#### **7.5 Alliance Executive Committees approve**

The IRC recommendations are then considered by the GAVI Alliance Executive Committee who approves funding for countries and this is then sent out to countries.

#### **7.6 Communication to countries**

The GAVI Secretariat communicates to countries the review results and if approved the details and timeframe of GAVI support to the country.