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Report of the Independent Review Team Examining  
The Advisory Committees of the WHO Department of  
Immunization, Vaccines and Biologicals

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January 2007

The Independent review team alone is responsible for the views expressed in this document .  
These views do not necessarily represent the decisions, policy or views of the World Health  
Organization

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## Executive Summary

*The vaccine world is changing and with it the demands and expectations of the research community, donors, global and national policy makers, and other interested parties. These changes include new vaccine development, technologies, optimizing programmes, vaccine safety issues, the regulation and approval of novel vaccines (including prequalification of vaccines for use by United Nations agencies, and increased funding flowing through new financing mechanisms). Such changes place a special responsibility on WHO to respond effectively. The future, as envisaged by the WHO and its UN partner, UNICEF, is described in the GIVS (2006-2015) and in the mid-term strategic plan of IVB.*

*Given this dynamic environment, it is timely that the IVB has asked for a review of its advisory structures, which is the subject of this report. The purpose of the review has been to examine the committee advisory structure supporting and serving the IVB, to determine the most essential and important elements, and to make recommendations where possible for more efficient operations in the future.*

*Altogether, 24 committees were originally identified for the review team as serving IVB in an advisory role. Most are standing committees, some are time-limited. Approximately one-half serve the research function of IVB and have a highly scientific and technical focus. While all these advisory committees serve crucial functions, the review team (RT) concluded that there is a lack of overarching policy and systematic communication channels to provide a framework for optimal articulation and functioning of IVB advisory committees (ACs).*

*The modus operandi of the RT has been to analyze the current situation, and to conduct a series of interviews - 18 internal and more than 28 external, as well as a round table consultation. In this way opinion and experience were solicited both within the department and outside it from interested partners.*

*The RT aimed to achieve the following:*

- simplification of the present advisory committee structure;*
- clarification of logical lines of reporting, advice and information exchange within IVB, and onwards to the DG of the WHO;*
- definition of the elements necessary for the successful operation of committees, including proper terms of reference (TORs) and regular review of their functions and activities;*
- an exploration of the central and critical role of SAGE, and of both the merits and weaknesses of the current practices of SAGE insofar as they might affect the optimal role of ACs; and,*

- *identification of cross-cutting issues that influence the efficient operation of the advisory committee system within IVB.*

*Figure 1 on page 12 depicts the proposed advisory committee structure and reporting lines.*

*As part of its work, the RT identified a set of elements and characteristics that it regards as essential for the effective operations of an advisory committee.*

*The RT noted that SAGE has a central and overarching role in the effective operations of the advisory framework serving IVB. The TORs, expectations, limitations, merits, and envisaged strengthening of SAGE proposed by the RT for this particular purpose are referred to in the body of the report.*

*The RT also noted that no accepted and consistent definition of an advisory committee exists within IVB, or indeed within WHO. The RT report proposes that this be addressed and has suggested a definition in the report.*

*In the conduct of its review, the RT identified a number of cross-cutting issues common to most, if not all, of the advisory committees of IVB. These are as follows:*

- *The need to strike a balance between addressing and taking care of conflicts of interest on the one hand, and consulting with and including the best available people on the other, when such people may have a conflict of interest either through their academic work and consultancies, or through affiliation with industry;*
- *The importance of balancing protection of institutional and committee memory in committees and retention of the best expertise available, on the one hand, against the imperatives of changing static membership and refreshment, on the other, and promoting and expanding competence in highly technical and specialized areas covered by advisory committees.*
- *The critical position of research and evidence in the work of IVB, and the necessity of appropriate committee structures and practices to inform the research arm of IVB.*
- *Participation of developing countries in the advisory committee structures, both for the insights that committee members from such countries bring and for capacity development.*
- *Inclusion of the regions in the advisory committee system to enhance the relevance and credibility of ACs.*
- *Need for clearer communication and better defined reporting channels between committees.*

*In making its recommendations, the RT considered the following to be of importance:*

- *identification and consolidation of functional groupings;*
- *ensuring coherence of recommendations made by the RT with the GIVS, and with the departmental strategic plan;*
- *identification and articulation of the elements of success and failure for an AC, and of the characteristics of the ideal committee; and*
- *simplifying the current advisory committee structure while recognizing that there are some gaps where the creation of new ACs might be useful, or where it may be necessary to expand the present scope of some extant committees.*

*In pursuing its task, the RT did not:*

- *Comment in detail on the TORs and justification of each of the 24 committees;*
- *Consider changes to the present chain of command and reporting structures within IVB; or*
- *Attempt a cost-benefit analysis of the present committee structure and operations, since insufficient data made such an exercise impossible.*

*Based on its deliberations and findings, the RT recommends as follows:*

1. *That IVB affirm the critical value and importance of the advisory committee structure as an effective means of obtaining expert advice and achieving a credible basis for policy making.*
2. *That the revised advisory committee structure and relationships depicted in the organogram (page 17) be adopted.*
3. *That SAGE be recognized as the key committee which reviews and/or makes recommendations to the Director-General of WHO on all aspects pertaining to immunization policies.*
4. *That SAGE and its working groups be adequately supported in order to meet the expectations placed upon it, including and especially the need for SAGE to have the necessary multidisciplinary expertise.*
5. *That a much stronger connection be established between the regional TAGs and SAGE (along with the rest of the IVB advisory structure). Immediate steps should be taken in this regard that would include strengthening of the regional TAGs.*

6. *That a definition of an advisory committee be determined by the department and adhered to.*
7. *That IVB adopt, for general application, the proposed criteria for a sound and effective committee; and that committees presently in existence that do not meet these specifications should be either upgraded or discontinued.*
8. *That the creation of three new ACs be considered to address the necessary issues of Quantitative Implementation Research, Regulatory Affairs (including the prequalification of vaccines), and Technologies.*
9. *That IVB should implement a comprehensive communication strategy [along the lines set out in Annex 8].*
10. *That the independence of advisory committees be affirmed as essential for their success, including the independence of committees from donors and from the advocacy functions of WHO itself.*

## 1. Introduction

The Department of Immunizations, Vaccines and Biologics (IVB), WHO HQ is advised by a number of advisory committees (ACs) that provide external expert opinions to the Department. The advice of ACs assists WHO in formulating global vaccine and immunization policies and strategies.

The members of these advisory committees are usually appointed by the Director of the IVB Department, the Director of IVR or in some cases by the Director-General of the WHO.

The AC committees of IVB generally meet at least once a year, and they constitute an essential part of the *modus operandi* of WHO. In some committees a considerable amount of work is conducted between meetings.

There has been a proliferation of such committees in recent years without a proper system or defined norms to guide the establishment and disestablishment of such committees, or to ensure regular review of the performance of committees.

With this in mind, the Director of IVB decided to conduct an external review of the advisory committees. A Review Team (RT) was established consisting of Dr. Bjorn Melgaard (Chair), Dr. Regina Rabinovich, Professor Peter Folb and Dr. Peter Figueroa.

The TORs for the review were developed after wide consultation and they are included in this report as Annexure 1.

The objectives of the review were as follows:

- To conduct a thorough review of the scope and roles of existing advisory committees for vaccines and immunization, particularly those internal to WHO at HQ and regional levels, and with due consideration to key advisory groups from partner organizations. The review should also consider other committees and structures not specific to immunization but which may at times issue recommendations with direct or indirect bearing on immunization.
- To review the relevance and roles of IVB committees in the context of the GIVS, a restructured SAGE, the core functions of WHO and partners, and how other ACs feed into SAGE and

policy making.

- To provide recommendations to adjust the structure of existing WHO IVB committees, their composition, and terms of reference to achieve the alignment, linkages, and integration needed for a coherent foundation for SAGE and other policy-making activities. The RT was asked to take into consideration the various types of advisory committees (strategic, managerial, policy setting, technical.) and to offer recommendations consistent with WHO's general rules on expert and scientific advisory committees.

The RT identified the need for expertise in communications to complement the analysis, conclusions and recommendations of the team. A communications expert, Mr. Peter O'Malley, was therefore contracted by IVB to assist the committee in its work. The TOR for this task is included in Annex 2. His assessment report is attached as Annex 8.

The review started in early September 2006 and completed its report in January 2007.

The team reviewed an inventory of advisory committees directly under the aegis of the Department as well as a number of other relevant committees within and outside WHO. It conducted broad consultations with WHO staff, and with partners and stakeholders outside WHO.

The conclusions and recommendations presented in this report are purely the responsibility of the Review Team. The team thanks partners inside and outside WHO who provided their views and suggestions to the Committee. Special thanks go to Dr. Okwo Bele, Director IVB for inviting us to do this review and to Dr. Philippe Duclos and Ms. Assil Farah of IVB who has provided invaluable support to the committee. Dr. Mohammed Ali Jaffer, MOH Oman provided specific and detailed suggestions to the RT, for which the team is grateful.

## **2. Background**

WHO has a dual mandate of providing global policies, standards and norms as well as support for member countries in applying such policies and standards to national programmes.

The WHO core functions have been defined in the Eleventh General Programme of Work, WHO 2006 as:

- Providing leadership on matters critical to health, and engaging in partnerships where joint action is needed;
- Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
- Setting norms and standards and promoting and monitoring their implementation;
- Articulating ethical and evidence-based policy options;
- Providing technical support, catalysing change and building sustainable institutional capacity; and
- Monitoring the health situation and assessing health trends.

Over the past decade, the global immunization landscape has changed substantially. There are now many more stakeholders in the vaccines and immunization arena than previously. At the same time, the scope of immunization efforts has broadened with the need to target other age groups, with an increased number of new vaccines and technologies becoming available, and with a renewed emphasis on provision of other critical health interventions at immunization contacts (e.g. malaria control and nutrition).

The Global Vaccines and Immunizations Strategy (GIVS) 2006 – 2015 is a joint UNICEF/WHO plan which has been developed through extensive consultation with partners. It has been endorsed by WHA (WHA 58.15) and the UNICEF EB (2005/7).

It comprises four strategic areas:

- Protecting more people in a changing world;
- Introducing new vaccines and technologies;
- Integration immunizations, other linked interventions and surveillance in the health systems context; and
- Immunizing in the context of global interdependence.

Each strategic area contains a number of implementation strategies, altogether 24. For each, a number of activities are listed.

WHO plays a unique role in the global vaccine research, introduction and implementation system. Its role as a lead health technical agency results in a programme and related advisory structure that provides leadership and technical guidance over a wide range of activities, from the research, the selection of quality vaccines for effective prevention, the technical guidance to the national immunization programmes that results in programme effectiveness and sustainability. New financing structures, such as GAVI, provide the resources for procurement and introduction of new vaccines. The rapid change in the global immunization scenario due to new vaccines and related technologies has created challenges as well as opportunities.

Managing that change requires that advisory structures, once designed to manage evolutionary changes in the program, be made more effective and efficient. In just the past 2 years, two new vaccines that can be introduced in infancy to prevent important killers of young children – rotavirus and pneumococcus – have been licensed and financed. In the past, the world waited for a trickle down effect of increasing global supply, and a gradual increase in marginal production at a marginal price, to begin to create supply for developing countries. Now, it is no longer the lack of resources that prevents children in the poorest countries from receiving these vaccines. The availability of new vaccines and financing has exposed the other critical elements required for introduction and sustainability:

1. **Information.** Data for decision-making includes burden of disease prior to vaccine introduction, impact assessment following introduction, and cost effectiveness, at least at a regional level.
2. **Research and development of needed vaccines.** Data must be generated from developing countries for priority vaccines that will be primarily used there. Global prioritization is critical to begin to ensure that the right vaccines are developed.
3. **Appropriate technology.** Rather than waiting for a next generation vaccine, the rapid transition to a developing country market means that regional and national data (regional efficacy and/or effectiveness; appropriate packaging, formulation and cold chain requirements) must be available to guide decision-making at

the national level.

4. **Regulatory framework.** Necessary data and systems to facilitate rapid licensure are mostly lacking for the neglected diseases which do not have a global market. Prequalification facilitates national approval, but itself requires a WHO recommendation to enter the prequalification queue. Linking these activities, even moving forward in parallel where possible to avoid delay, has become increasingly critical to avoid these global procedures becoming barriers to access.
5. **Supporting policy.** What to introduce, how to prioritize, and how to optimize the program to manage change, country demands, and a host of challenges raise critical questions. A robust and clear policy process would mean that global priorities for vaccine development were recognized, that investments by donors were aligned with these priorities, and that industry developed the needed vaccines in a relevant format. Gaps in the process results in costly mistakes and delays.
6. **Impact and safety data to guide usage.** As vaccines are being introduced in both developed and developing countries, systems to evaluate impact and safety become even more important. For vaccines that will only be used in the developing countries, the relevant data must be generated by the countries affected.
7. **Implementation research.** Targeting improvements in immunization technologies, from temperature monitors to tracking systems, becomes crucial as the new vaccines are introduced, to reduce wastage and optimize resources.

### *The role of ACs*

WHO is traditionally advised by external bodies, including expert panels and scientific groups. While a formal process exists within WHO for appointing expert panels, the majority of committees and working groups guiding WHO's work falls outside the formal category of expert panels and committees.

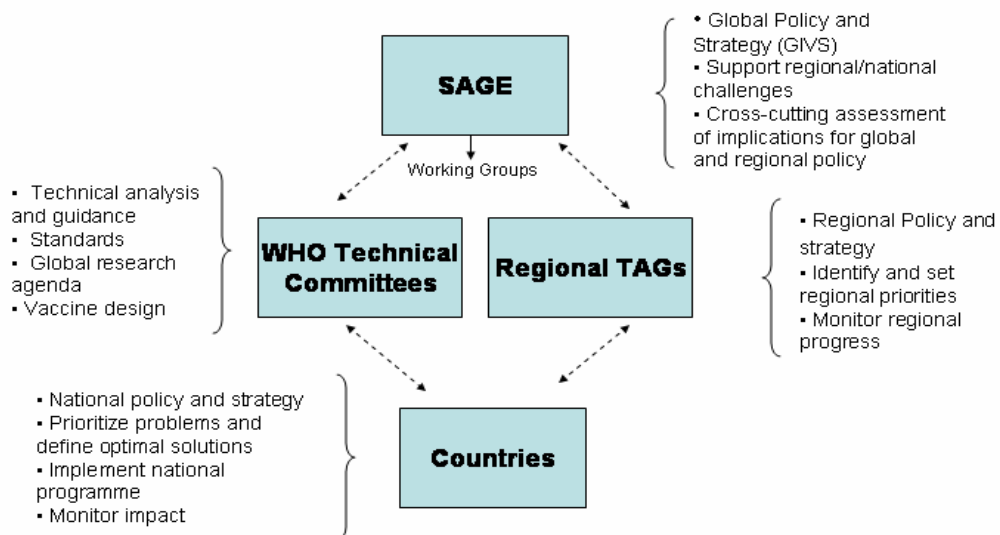
This also applies to the work of the Department of Immunization, Vaccines, and Biologicals (IVB) in WHO, HQ. Over the years, with the broader scope of issues to be tackled at global, regional and country levels in the areas of standards setting, vaccine development, and

immunization, including research, many specialized advisory committees have been established.

The structure and operating mechanisms of the existing IVB ACs may no longer be appropriate or optimal to meet the challenges arising from the changing global environment. Furthermore, a number of the IVB committees have gradually become increasingly independent and somewhat distant from each other, with a resultant loss of synergy and coherence in formulation of policies and recommendations.

The RT has developed a framework that provides an overview of the various key functions and role of ACs at different levels, as depicted in Fig. 1 below.

**Fig 1: WHO Immunization Functional Policy Advisory Framework**



### *AC Reporting Lines*

The reporting lines of ACs vary considerably, and there is no clear link between many of the committees. The RT believes that this disconnection may lead to duplication of work and possibly conflicting recommendations. There is a clear need to establish a sound link and agreed relationships between ACs.

### *Main IVB ACs*

A recent inventory of IVB ACs shows that there are presently 24 such groups providing advice to the department. This list is included in the RTs Terms of Reference in Annex 1.

Four main cross-cutting committees are involved in providing information to WHO in the policy/normative area:

- the Strategic Advisory Group of Experts (SAGE), which has recently been restructured to respond to changes in the field;
- the Expert Committee on Biologicals Standardization (ECBS);
- the Global Advisory Committee on Vaccine Safety (GACVS); and
- The Advisory Forum for Vaccine Research (IVAC), which is currently being restructured to oversee all the R&D work of IVB.

The RT has applied the following definition of an AC for its work:

*“An advisory committee is a group of external experts within a well-defined technical area. “*

(A more complete definition of the general characteristics of an AC is presented on page 14)

### *The Role of Regional ACs*

Technical advisory committees have been established at the regional level over the last decade. While names differ between regions (TFI, TCG, ETAGE, TAGs) their functions are essentially similar: to provide technical advice to the Regional Director on vaccines and immunizations relevant to the countries in the region. (In this report the term TAG will be used to describe all regional vaccine advisory committees.) The operations of these committees are similar, with annual meetings being held in some regions jointly with meetings of National Programme Managers.

The regional advisory committees fall, in principle, under the purview of Regional Directors. However, their functions and involvement with global ACs have been included in this review since the interaction

between TAGs and IVB global committees is an essential component of the work of each.

### **3. Review Methodology**

The first step in this review was the development of an inventory of all ACs in IVB. A standard set of information about ACs was collected from IVB staff. It included the TOR for each AC, reporting lines, membership and the latest meeting report.

The RC has reviewed a range of documents during its work. (See Annex 4)

Using this inventory, a series of consultations were conducted by the RT members. The consultations included interviews with IVB staff and other key informants within WHO HQ, as well as Regional Advisers. Additional interviews were conducted with partners and stakeholders. (See Annex 3)

The review committee held two face-to-face meetings, in September 2006 and January 2007, and a number of teleconferences. RT members also participated in the ETAGE and SAGE meetings, as well as the Global Vaccine Research Forum that was held within the review period. During the latter, a round table session was organised to consult a number of partners in the international vaccine research and development community.

### **4. Findings and Recommendations**

#### **4.1 Findings and Recommendations Regarding The Organization and Structure of Advisory Committees**

##### *Defining an AC*

The WHO basic rules stipulate how “expert panels” as well as study and scientific groups are to be established, and committee meetings held. Only one IVB committee – ECBS – is, in fact, an established formal WHO expert committee.

The concept of study and scientific groups is rarely used nowadays. Many WHO advisory committees will, in principle, fall under these categories without formally being designated as such.

The WHO rules for these study and scientific groups are rarely considered when new committees are established. They are thought to be too cumbersome and slow as memberships, meeting agendas, schedules and reports all have to be approved by the Director-General. The reports have the advantage of being formalised by the Executive Board of WHO and as such endorsed by member countries. The rules for external expert advice are currently being revised. The RT has examined the WHO rules, and is of the opinion that these guidelines as they are at present are limited relevance for the IVB committees under review.

*An advisory committee is a group of external experts:*

- *appointed by a thorough selection process by a Director or a higher-level manager*
- *within a well-defined technical area;*
- *with expertise at highest level;*
- *selected through a transparent selection process; and*
- *serving for a fixed period.*

*An advisory committee:*

- *provides policy and technical advice in a specific area, based on solid scientific evidence, to a WHO senior manager at the level of director or higher;*
- *has clear TORs to guide its work;*
- *consults widely as and when necessary*
- *meets regularly, but can be time-limited or permanent, with a clear mandate;*
- *is administered by WHO secretariat;*
- *issues reports to WHO with conclusions and recommendations, and provides the evidence on which such conclusions and*

*recommendations are based; and*

- *acts without conflict of interest.*

The review team was unable to identify any consistent terminology or definitions of ACs within WHO. A variety of terms are used to describe ACs within IVB and WHO without clear and consistent rationale or definition. In practice, an AC may be designated as an advisory committee, an advisory group, a steering committee, an expert committee, and expert advisory group, or a technical advisory group with or without the designation *ad hoc*.

The RT is of the view that it would be useful to have clear definitions, and a simplification of terminology, with respect to WHO ACs as well as generally applicable and consistent guidelines for selection and rotation of experts. The RT was advised that WHO is presently addressing this, and that it is the subject of an ongoing review.

#### *Identifying and assessing IVB ACs*

An inventory of existing ACs was developed as the first phase of this review. The inventory registered IVB 24 committees. Thirteen (13) deal with R&D subjects. After interviewing IVB staff, the RT concluded that five of the listed committees do not actually function according to the definition used in this review, some being internal WHO WGs, and others open forums for dialogue and information-sharing. Two (2) committees do not presently exist but they have been proposed. They will be considered later in the report. (See Annex 9).

The remaining 19 meet the RT's definition of an AC, and have been categorized by the RT in accordance with their contributions to strategies within GIVS and the strategic plan for IVB, respectively. Mapping of AC roles to overall strategic objectives shows that only one committee – SAGE – is truly crosscutting, in that it covers all strategies in both strategic documents. (See Annex 5)

In a further categorization, 13 out of 19 IVB ACs contribute directly to R&D. Two are time-bound and project oriented.

The RT has reviewed the relative global importance of the IVB ACs in order to establish a hierarchy, within and between committees. The SAGE stands out as the main overarching committee that advises the DG

of WHO on global policy matters pertaining to vaccines and immunization. (The TOR for SAGE is in Annex 6.)

Three other IVB committees also have mandates that are crosscutting: GACVS, ECBS and IVAC

### *GACVS*

GACVS was established in 1999 and has developed into a high-powered committee widely respected for its independent, scientific work.

Its TOR stipulates the remit of the GACVS to include all issues of vaccine safety. The committee provides scientific advice to the director of IVB and to SAGE, and a report is delivered at each SAGE meeting on the activities of GACVS. The report is for the information of SAGE, and it is recognised that GACVS, by nature of its work, retains an independent status from SAGE.

GACVS has a public WEB site that presents a summary of the work of the committee. It further supports a vaccine safety network which provides the committee with inputs for its work.

There are 14 members of this committee, nominated by the responsible WHO staff, and appointed by the Director of IVB. Members rotate every 3 years. There is currently no cross-membership with SAGE but the Chair of GACVS is invited to SAGE meetings and the Chair of SAGE to GACVS meetings.

Significant work is carried out between GACVS meetings, and a restricted access WEB site is maintained for the interactions of the committee.

The GACVS reports to the Director IVB. Its reports are distributed to a fixed distribution list, and a summary version of each report is published in Global Immunization News (GIN) and in the WER.

### *ECBS*

ECBS was established in 1949. It is the only expert panel advising IVB that operates under the rules for WHO expert committees. The committee deals with vaccine standards and delivers specialized and technical advice on global standards and biological reference materials. Its work is considered essential to vaccine development and production, and is

highly regarded for its integrity, and for meeting the highest scientific standards.

ECBS has 10 members whose participation varies according to the agenda items in meetings. The inputs to ECBS meetings are prepared by a range of study groups which meet between the main meetings. All members of ECBS study groups are drawn from an ECBS expert panel.

The committee uses a secure online information-sharing and collaboration tool for work between meetings. It reports to the Director IVB, and its reports are also provided to SAGE. Reports from ECBS are published in the WHO Technical Report Series.

### *IVAC*

IVAC is currently being reconstituted. The TORs available to the RT do not conform with the inventory requirements and may be out of date. The AC is due to meet in early 2007 and the TOR may be revised during the meeting. The current list of members includes representatives of various partners selected for their institutional affiliations rather than their expert knowledge and experience. The RT has not had the opportunity to discuss the TOR further with the Department but nonetheless it recognizes the critical role for an AC that oversees technical R&D committees and advises IVR on strategies, priorities and gaps.

### *Other IVB ACs*

The Global Commission on Polio Eradication is an independent commission listed in the inventory. As a commission it has a special status and is not considered further in this review.

There remains a total of 14 ACs of which two are time-bound. Excluding the latter from analysis leaves 10 with various R&D mandates and 2 dealing with immunization aspects (AC on training and AC on polio eradication).

During the time of the Review Team's work, IVR planned a restructuring of its advisory structure. The restructuring includes sunseting 4 active committees: Dengue/JE; New delivery systems; TB vaccines; and Measles/rubella research. All 4 of these traditionally reviewed proposals for funding and will be replaced by Ad Hoc consultations as needed.

The restructuring of R&D component of the advisory structure presented in figure 1 points to three types of different kinds of work that are done by the program:

- Cross vaccine R&D Strategy – IVAC
- Time-limited external advice to guide an R&D program, either external or internal project advisory committees (aerosol measles, meningitis PAG)
- Priority vaccine R&D areas with a disease focus (malaria, HIV, TB, HPV, Diarrhea, AAVP).

In addition, two new committees are being considered: QUIVR – Quantitative Implementation Research; and Pandemic Influenza GAP which as a priority and new activity will be a joint activity between IVR and the Global Influenza Program.

*Table: Revised (proposed) advisory committee structure*

Committee	Focus	Participants	Scope
IVAC	Cross-vaccine R&D advice.	Global partners in vaccine R&D	Strategy, cross-disease synergies
MALVAC	Malaria Vaccines	Scientific experts and key partners	Strategy, program
VAC	HIV Vaccines	Scientific experts and stakeholders	Policy areas; protocols, and proposals
STOP TB VAC	TB Vaccines	Scientific experts and stakeholders	Program activities.
HEAG	HPV Vaccines	Scientific experts and stakeholders	IVR + other WHO programs on HPV vaccine
SC- VDD	Diarrheal Vaccines	Scientific experts and key partners	Reviews proposals, reviews field
AAVP	African AIDS Vaccines	African experts	Strategy for African AIDS Vx programme; Decides on funding envelopes
Pandemic Influenza	Influenza vaccines	Country representatives and donors/partners	TBD
QUIVR	Implementation research	Scientific experts	TBD

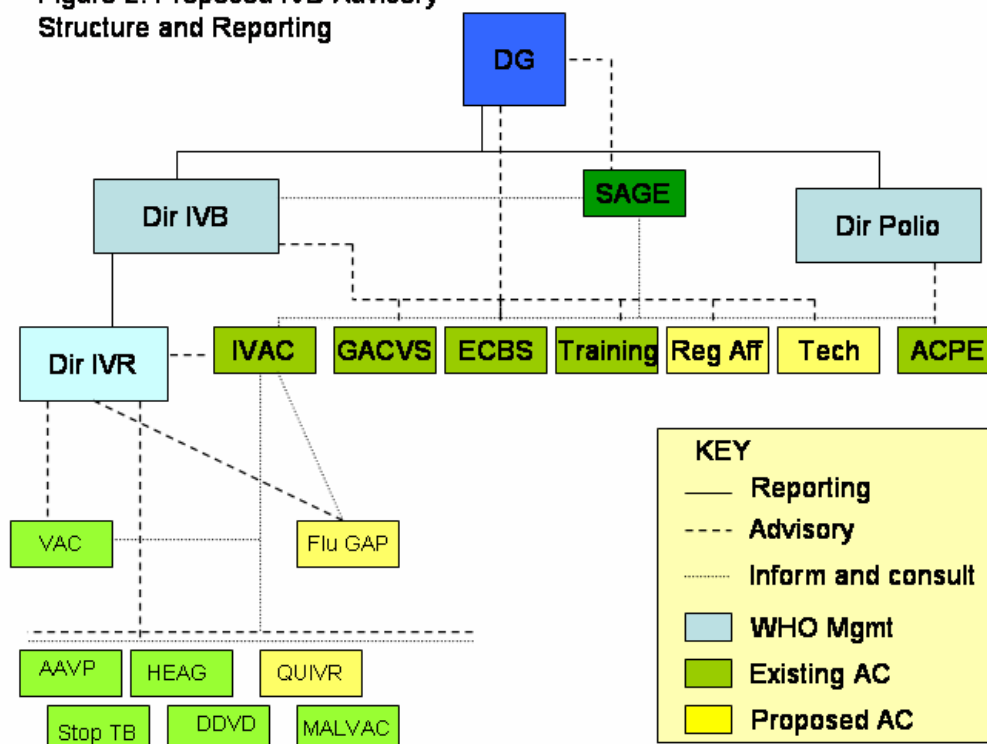
The result of this restructuring would be 8 R&D ACs for the unit – a reduction of 3 committees overall plus the committee under the global influenza programme overseeing vaccine development.

The RT has reviewed the TORs of the AC on training and the AC on Polio Eradication and considers them relevant and appropriate.

The RT has noted proposals to establish four additional committees. They include the two committees proposed by IVB for prequalification and for National Regulatory Authorities, respectively, and two additional ACs for regulatory affairs and on logistical/technical issues. It has been suggested that the three proposals dealing with regulatory aspects might be combined.

The review team proposes a system with reporting lines as in Figure 2 below.

**Figure 2: Proposed IVB Advisory Structure and Reporting**



The relevant reporting relationships within the WHO management structure are shown by the continuous lines. The dashed lines indicate the specific WHO Director to whom the AC reports.

The SAGE and ECBS report to the DG of WHO. The GAVCS, and the proposed regulatory and technology committees report to the director IVB and the research committees report to the director IVR, as does the proposed IVAC. The ACPE reports to the Director of Polio who resides in a different division within WHO.

The dotted lines indicate the need for ongoing systematic information sharing and consultation. Each advisory committee conducts its deliberations and makes its conclusions and recommendations in an independent manner. However, often the recommendations from one committee relate to the work of another committee and need to be taken into account.

The SAGE has a central role in this respect because its terms of reference require it to consider the implications of recommendations from other ACs in relation to global and national immunization policy.

The reports of all IVB ACs need to be submitted to SAGE. The reports of different R&D committees should be submitted to IVAC which, in turn, would present its report to SAGE. The intention is not for SAGE to approve or not to approve the conclusions and recommendations of other ACs. SAGE needs to be informed of the work of the ACs in order to better formulate global immunization policy. SAGE also needs to provide critical feed-back to the other ACs.

#### *Relevant Non-IVB ACs*

The review team also considered a number of committees outside IVB, within and outside WHO. While several contribute to the vaccines and immunization area, none appears to have significant policy implications or to overlap with the IVB committees. One committee – the Essential Drugs List Committee – has global policy implications for the immunization field. However, it draws its entire contributions from IVB and its ACs, and it has been decided to remove vaccines from the list in the future.

#### *Budgets for ACs*

The budget for meeting activities for the IVB ACs for the biennium 2006-2007 amounts to 2.8 million USD for 17 planned meetings (Annex 7). (The polio ACs are not included, as they are not organised under IVB).

The budget for two planned meetings for each AC during 2006-2007 is 200.000 USD. The standard budget for one committee meeting is 90.000 USD. It is not expected that the actual total expenditure will deviate significantly from the budget.

The total IVB budget for 2006-2007 is 71.845 Mill USD of which 41.578 USD is for activities, and the rest for salaries. The budget for AC meetings constitutes 6.7% of the total activity budget.

### *Conclusions and recommendations regarding committee structure*

1. The Review Team affirms the critical value and importance of the advisory committee structure as an effective means of obtaining expert advice and achieving a credible basis for policy making.
2. The Review Team recommends simplification and consolidation of the advisory structure, as well as a clarification of the present reporting and communication lines (see Figure 1).
3. The review team urges IVB to develop a clear definition of an advisory committee to the department, and to adhere to that definition. IVB should also adopt, for general application, the proposed criteria for a sound and effective committee (See page 33). Current ACs that cannot meet these specifications should be discontinued or, alternatively, upgraded.
4. The WHO general rules for expert panels should generally not be applied to existing ACs (except to ECBS) or to new expert committees.
5. The review team supports the creation of three new committees to address the issues of Quantitative Implementation Research, Regulatory Affairs (including the prequalification of vaccines) and Technologies.
6. The proposed changes in the vaccine R&D advisory structure (sunsetting 4 committees and creating two new committees) are appropriate and are endorsed. The resulting 9 R&D committees (incl. the influenza AC) cover the breadth reflected in the global program and its strategic plan.
7. It was noted that Pneumonia vaccines are not considered under this structure. Considerations must be given by IVR to decide on how

ALRI prevention through vaccines are to be addressed as this is clearly a global priority. While the R&D committees advise IVR, they must be aligned with SAGE as the overarching committee.

8. While not every expertise across all field will sit at SAGE at any single timepoint, it is crucial that SAGE members be able to grapple with a broad array of issues, interacting back with the R&D committee when issues are contentious or more information is needed. Some topics will require close interaction to solve.
9. One opportunity for close alignment from R&D committee to SAGE is that members of the R&D committee participate in the SAGE working group.
10. The review team agrees with the central role of SAGE as the main committee that reviews and makes recommendations to the DG on all aspects of global immunization policies.
11. SAGE and its working groups should be adequately supported in order to meet the expectations placed upon it, including and especially the need for SAGE to have the necessary multidisciplinary expertise.
12. The review team urges closer consultations between the regional TAGs and SAGE and the rest of the IVB advisory structure. Immediate steps should be taken in this regard, including the strengthening of the regional TAGs.
13. A clear procedure is needed to guide the establishment of any new AC. A decision to create an AC should include analysis of duration of need, specific Terms of Reference, potential usefulness of *ad hoc* meetings as an alternative, and consideration of potential fit with existing ACs.
14. As a general principle across the program, all committee functions should be reviewed as a vaccine field matures and enters into the EPI.
15. IVB should implement a comprehensive communication strategy, along the lines described in Section 5.2 below, and in the communications annex (Annex 8).
16. IVB should affirm that the independence of advisory committees is regarded as critical, including the independence of committees from donors, and from the advocacy functions of WHO itself.

17. The ACPE for polio, although reporting to the director of polio, should submit a report to SAGE, and clear recommendations should be requested from SAGE by the ACPE.
18. The opportunity for capacity building must be considered in the work of all ACs. The RT provides some salient points to this aspect in the box below.

**CAPACITY DEVELOPMENT**

*An important and necessary aspect of the work of the advisory committees is the fostering and encouragement of expertise and of individuals with special skills. It is an investment for the committees, as well as for countries and their national and regional programmes, when people become members of advisory committees. Their views and experience can be invaluable for the committees concerned, bringing to the committees a special perspective of the developing world and raising questions that do not necessarily occur to scientists and clinicians working in more affluent countries. Moreover, such members of committees are likely to have a fine and realistic appreciation of conditions on the ground in countries that often have the highest burden of infectious diseases. It should be an essential part of the work and functions of all committees of IVB (indeed, of all WHO committees) that their membership and decisions support the development of capacity, including research capacity and human potential. The review team regards the advisory committees of IVB in the same light.*

**4.2 Key findings and recommendations related to setting agendas, preparing meetings, papers and studies and other inputs.**

The RC analysed the manner in which AC meetings are prepared, the agenda set and policy papers presented to ACs. This aspect has been probed particularly with regard to quality of papers, and the agenda-setting process.

### *Agenda setting*

The SAGE agenda is set by the Chair and the secretariat after consultations with the SAGE members and the RAs.

Following the April 2006 SAGE meeting, the SAGE secretariat undertook a systematic review of agenda items for the coming meeting. The secretariat's list of candidate agenda items was shared with RA's, SAGE members and partners invited to SAGE. IVB staff are also involved, often trying to secure a slot on the agenda for their particular technical area. Based on the comments received, the SAGE Chair and secretariat proposes the items to be included in the following meeting.

It is noteworthy that two of the topics for the most recent SAGE meeting were actually proposed by regions. The process of selecting agenda items is, however, not perceived by many involved parties as sufficiently systematic, especially with regard to consultations with TAGs (see special theme on SAGE/TAGs in section 5.2 below).

Agenda items are initially classified for SAGE as being a) for information, b) for discussion, or c) for decision.

The Director presents his report to SAGE, including the status of implementation of previous recommendations as the first agenda item in the meeting.

Three regional advisers present reports at alternate SAGE meetings, where they are asked to highlight regional priorities and major policy issues and implementation. The purpose is to provide SAGE with background information that helps SAGE in defining global immunization priorities.

The development of position papers is a specific policy development methodology used by SAGE for individual vaccines.

- Position papers are based on a review of available information on a specific infectious agent and the antigens targeting this agent, followed by a consultation process involving various interest groups.
- A consultant drafts a formal position. The initial draft then undergoes an extensive review by industry, regional offices, key interest groups and key area experts. The papers are then prepared

and endorsed by an internal editorial committee in IVB.

- Finally, position papers are presented to SAGE, and become policy only when endorsed by SAGE.

This process is widely respected as a sound and robust way of setting global vaccine policies. It should be continued as major policy setting mechanism.

The agendas for other ACs are normally set by the Chair and the secretariat with little consultation outside the committees. This appears to work well for ACs other than SAGE as the process was not challenged during the RT consultations.

### *Studies and papers*

SAGE is presented with papers for each agenda item. The nature of these papers varies. Some items are subjected to extensive research in advance, and detailed studies or reports are presented to SAGE. Others are programmatic progress reports with little or no specific research being presented. Some papers are prepared by the secretariat in collaboration with individual SAGE members, and some without prior involvement of SAGE.

The “new” SAGE has established working groups for selected agenda items to prepare papers for the meetings, and to assess specific technical issues.

The RT found a broad consensus that this new approach constitutes a marked improvement over the way SAGE functioned in the past. Concern, however, was expressed over the composition of working groups, which are not always considered sufficiently broad or inclusive, and which may not always involve the best available expertise. For its part, industry feels it is not adequately heard.

The WGs under SAGE are chaired by a SAGE member and comprised of different experts, depending on the subject. At the most recent SAGE meeting, three WGs presented reports (on measles, pneumococcal vaccines and conjugate vaccines, respectively.)

The Chair distributes specific agenda items in advance of the meeting to individual SAGE members, asking them to review the item, and to be prepared to present their summary of the item to the full SAGE. A

“yellow book” is prepared with most of these papers and distributed to SAGE. This is another major improvement over past reports. However, the book could be made more usable by better editing and presentation (e.g., with specific reference for each paper to the relevant agenda item.) The regional reports constitute nearly half the volume. Guidelines for regional reports would be useful.

Papers are posted on a protected WEB site prior to the meeting. However, all observers do not know this, nor is it mentioned in the invitation letter. Invitations to SAGE should include reference to the WEB, and notice should be sent by email every time a new paper is posted.

### *Collaborating centers and panels of experts*

There are no established panels of experts within the technical areas of IVB, except ECBS. Each staff is expected to have a broad knowledge of their field of expertise and to draw individuals from this field for various assignments related to the AC work.

This process is not always comprehensive or inclusive. It has been suggested that WHO staff might actively maintain a panel of experts/centers of excellence/collaborating centres that can be used as needed. A formal recognition as panel member /institution would help recruit experts for specific tasks.

In the view of the RT, WHO Collaborating Centers (CCs) represent a core body of expertise available to WHO for expert advice. They are not systematically used by many parts of WHO and their role in AC work could be utilized more systematically than is the case at present. This applies also to the IVB ACs.

As reservoirs of expertise, the CCs should be tapped by IVB when nominations for new AC members are solicited, when working groups are established, and when quality control or peer reviews of papers and studies are sought. Technical units might be able to develop networks of CCs that systematically participate in the advisory work of the units, and the ACs. However, care would need to be taken not to devolve responsibility for the quality of papers from IVB to CCs.

### *Conclusions and recommendations*

1. The RT is encouraged by the process underway to strengthen the role and function of SAGE, including the selection of members, increased

transparency, agenda setting, preparation of documents and use of working groups.

2. One of the main tasks of SAGE is to assess the implication for global and national immunization policies of the recommendations of the ACs.
3. There is a need to develop a SAGE work plan with a medium-term perspective of 2-3 years to assist members in longer-term planning of their workload.
4. SAGE agendas should be carefully developed so as to avoid overloading and to facilitate full discussion.
5. The process used to develop and endorse position papers is seen as sound. It should be continued as major policy setting mechanism.
6. IVB should consider establishing and maintaining panels of experts in each technical area that are appointed by the Director, IVB. Participants in ad-hoc meetings and time-bound committees should be drawn from the panels. They could also be involved in preparing documents and performing studies to be addressed by IVB meetings.

#### 4.3 Findings and Recommendations Regarding Committee Meetings, Participation and Operations

The RC analysed the formal structure and operations of all ACs as reflected in the inventory and expressed in consultations with staff and external partners. This included the TOR, membership procedures, conduct of meetings and the features that characterize the “ideal committee”.

##### *Terms of Reference for ACs*

The Department, together with the current Chair, has pursued a reform of SAGE which receives praise from most partners and stakeholders. Among the strong elements of reform is the transparency that now surrounds the meeting and the work of the committee, the preparatory work conducted in working groups and the organization of recent meetings.

The SAGE TOR was completely revised in 2005 after a broad consultation process. The TOR is included in Annex 6.

There is little uniformity of TORs for other committees. However, TORs for a number of R&D committees are reported to be under revision, and are being streamlined in terms of technical substance, reporting lines, composition and rotation of members and frequency of meetings. Few of these committees have a formal relation to SAGE.

It is noteworthy and commendable that recent TORs of certain ACs include a clause calling for suspension of membership if the member is inactive. The recently revised TORs for several R&D ACs compiled in the inventory stipulate that reporting is to the Director, IVR.

A number of R&D ACs have traditionally had a grant-giving function based on limited budgets. Grants were given based on proposals reviewed by the ACs. Most stakeholders consider this function obsolete, and it has been abandoned by several of the ACs.

#### *Selection of SAGE members and chair*

Selections of new members of SAGE are now based on an open call for nominations as and when seats become vacant. This happens when the rotation principle dictates that a member leaves, or if a member is inactive. The invitation to nominate is published in WER, WHO Bulletins and on the WEB. A committee, with internal and external members, screens the nominations. The committee recommends candidates to the Director, IVB who, in turn, submits his preferred candidates for the DG who appoints new members.

The selection of members takes into consideration a number of criteria such as regional representation, technical areas of expertise and gender. Regional offices are encouraged give their views and to nominate candidates, but have no formal say in the selection process, and are not represented in the selection committee.

All members rotate in a staggered manner every three years, including the Chair. Membership can be extended once. The Chair is selected by the Director and confirmed by the DG.

It is a steep learning curve for a new member to adapt to the functions of WHO ACs. CDC is currently considering two induction initiatives to ease the work of new members and speed up their effectiveness. These include

an attachment of a new member to an established member in the beginning, and the development of a comprehensive orientation guide for new members. The review team suggests a similar initiative for IVB.

### *Selection of members of other ACs*

Selection of members to other committees is mostly an internal process within IVB. Suitable candidates are identified based on discussions within IVB and among key external partners, depending on the subject area. Regional offices are consulted in some cases. More effort is now invested in consultations with the regions than before, depending on the subject area.

Members of R&D ACs – for the most part – are appointed for one year, renewable for a maximum of two consecutive two-year terms. This appears to be standard in newly revised R&D ACs. The number of members varies from six to fifteen.

Regional offices feel that they have little involvement in the R&D area. However, they recognize that, even when they are invited to meetings, they frequently are unable to attend due to lack of capacity. Some improvements are underway with posting of R&D staff at regional offices funded by IVR. This will assist IVR in defining committees where regional attendance is most important.

### *Observers*

A large number of observers are invited to SAGE meetings to represent various stakeholders and partners. Industry has some reservations about observer invitations, and would prefer more observers from individual companies as and when the agenda involves specific companies. Otherwise, the range of invitees seems to include all relevant partners. Usually, many more observers are invited than actually attend.

For other ACs, observers are also invited depending on the agenda and the interested partners. There have been no reservations expressed during the consultations as to current practice.

### *Conduct of meetings*

All SAGE meetings take place in Geneva. Logistically it is difficult to move larger meetings outside the Geneva area. However, several

respondents proposed that more meetings – SAGE and not SAGE - be held outside Geneva to enhance the involvement of countries and regions.

There are two annual SAGE meetings. Meetings are usually held over two to three days, which is considered appropriate. Though many feel that the SAGE agenda is overloaded, there has been no interest shown in expanding the duration of the meeting.

The majority of the AC meetings are conducted in a traditional fashion: presentation of a paper, discussions lead by the Chair of the committee or a specially appointed Chair for the session, and a final concluding session with joint formulation of meeting recommendations.

SAGE has adopted some changes to this tradition including the abolition of the session on drafting of recommendations.

In-between meetings, activities vary considerably. The WG structure of SAGE is an example of such activities. SAGE also has teleconferences between meetings, but no decisions are taken on substantive matters during these conferences. Many committees are only active when they meet – usually once a year. However, both GACVS and ECBS have significant activities between meetings.

There are no standard operating procedures that guide the work of ACs. This has been pointed out by several respondents who have suggested that examples from other non-WHO committees be used to develop such procedures.

Industry expressed the need for more openness around GACVS, both in consultations and in obtaining information about adverse events.

### *Secretariat*

A well functioning secretariat with adequate capacity is considered essential for all ACs. In particular, it has been emphasized that SAGE needs a full-time executive secretary to optimize its role as the global policy setting body.

### *Conclusions and recommendations regarding committee meetings, participation and operations*

1. The approach taken in improving the composition and operations of SAGE is seen as an example that could be applied when other ACs are being revised or formed, including the regional TAGs.
2. There should be Standard Operating Procedures for each AC in IVB.
3. Induction time for new AC members is long and could be shortened by appropriate induction measures.
4. The capacity of the secretariat is critical for the efficient function of all ACs. SAGE should have a full-time executive secretary.
5. Industry expressed the need for more openness around GACVS. They suggest an advance meeting between industry, the GACVS chair and the secretariat.
6. The RT has formulated characteristics of the ideal committee that could be adopted in the management of IVB ACs.

## **Characteristics of the Ideal Committee**

The review committee canvassed interviewees in their views on the structure and functioning of the “ideal committee”. There was broad agreement that an effective and efficient advisory committee would have all of the following:

- A high level of collective expertise in its membership, representing global knowledge and skills, and appropriately representative demographically and by region;
- Nomination of the members of the committee should be by a transparent and objective process, and the respective skills of the members should be diverse as and when appropriate;
- Transparency in its conduct of affairs, and accountable, with a thoroughgoing commitment to ensuring that all its decisions and recommendations are based on best science and sound clinical practice, as well as a strong public health principles;
- There should be close consultation with the regions in the operations of committees;
- A strong, adequately resourced secretariat, regular meetings, and the opportunities to convene extraordinary meetings when necessary, and close links with the management of IVB and with the research programmes of the department; efficiency of the committee is of high importance;
- Clear and unambiguous terms of reference<sup>1</sup>;
- Preparing timely and easily accessible reports;
- Close links at all times with the research activities of the department, and with other existing programmes, if the decisions of the committee are to be appropriate and cogent; and
- Working groups to be established *ad hoc* by the Chair in consultation with the secretariat and with other members of the committee.

### **4.4 The preparation of reports, dissemination and public relations**

The RC, in its consultations and analysis, examined the way the outputs from ACs are formulated and disseminated in order to assess the quality of the outputs, and the reach and visibility of its work.

A separate communications assessment has been conducted and is summarized in section 5.3 below and in an attached report (Annex 8).

Some highlights from the consultations and RT analysis are:

- AC reports are generally thought to be of good quality.
- SAGE reports are published as meeting reports soon after the meeting in the WER and posted on the SAGE-dedicated WEB site.
- There was suggestion that some meeting reports could be written in a clearer and simpler language to make them accessible to non-professional policy makers. Consideration should also be given to asking regional offices to translate meeting reports of major ACs into more languages.
- A wider dissemination should target WRs, UNICEF reps and other decision makers not directly involved in the IVB programme.
- In general, advisory committees (including SAGE) need to be more visible and their major conclusions shared with media.
- SAGE conclusions should be disseminated to the public where relevant. There should be press releases and a press conference at the end of each meeting.
- A public web site should be developed that includes all policy recommendations from SAGE and other ACs.

Reports from other committees, except GACVS are usually more restricted in their distribution. They are generally considered of good quality. The ECBS is traditionally published in WHO's technical report series, but this usually happens long after the actual meeting. IVB should consider an alternative publication route for these reports.

Other reports are not normally published widely but are simply distributed to meeting participants and relevant partner agencies. This appears appropriate and sufficient. However, IVB should carefully consider the merits of a wider dissemination to enhance the visibility of committee work and the impact of AC recommendations.

## *Conclusions and recommendations*

1. The reports from ACs are generally of high quality.
2. SAGE meetings could usefully be followed by both press releases and a press conference.
3. Special efforts should be made to ensure that the SAGE report reaches more national programme managers, WRs and UNICEF reps.
4. A policy web site should be established by IVB and actively maintained.

(See the thematic section 5.2 below on communications and Annex 8 for additional commentary and recommendations on dissemination and communications strategies.)

## **5. Special themes**

### 5.1 Relations between SAGE and TAGs and between HQ and regions.

All WHO regions have ACs with TORs that are similar, and that operate in much the same way. These TAGs have different names in different regions (ETAGE, TFI, TCG, TAG).

The relations and interaction between SAGE and TAGs appear to be one of the weaker elements of the IVB AC operations. This applies to most aspects of SAGE's work and is particularly felt by the TAG Chairs, some of whom report that there is "a complete disconnect" between their work and that of SAGE.

The roles of TAGs vis-à-vis SAGE are not clearly specified, and the manner in which they ought to interact has not been well defined. While there is a systematic in-depth involvement of regional offices in agenda setting for SAGE, the involvement of TAGs, in particular, could be improved. The process of selecting agenda items is not perceived as sufficiently systematic, or consultative with TAGs. This is an opinion expressed by all TAG members consulted.

This gap is felt in spite of the fact that TAG chairs are invited as observers to SAGE. However, the regional consensus is that TAGs should have a stronger role in all aspects of SAGE activities, and not just

at meetings. In this regard, the RT noted that two TAG Chairs were members of the measles WG under SAGE, which the RT sees as a positive step.

TAG members/Chairs are not invited to other IVB AC meetings unless they participate in a different capacity other than being TAG members.

### *Conclusions and recommendations regarding relations between HQ ACs and regional TAGs*

1. There is a major need to improve the relations and coordination between SAGE and TAGs, including the agenda-setting for SAGE;
2. TAGs should be seen as advisory bodies to countries, translating global SAGE recommendations into regional policies;
3. TAG TORs and operating modalities should be revised with due reference to the SAGE reform (membership rotation and selection, agenda setting, conduct of meeting, secretariat support etc.);
4. TAG chairs or members should be selectively invited to other committee meetings as and when the agenda is regionally relevant; and,
5. Generally, TAG chairs should be more involved in SAGE. In particular, they should meet with the SAGE chair and the secretariat immediately prior to – and/or after - SAGE meetings, or at another suitable opportunity (e.g. a Chairs' meeting)

### 5.2 Communications

The attached communications report (Annex 8) contains observations and recommendations to enhance the communications practices and effectiveness of major advisory bodies to WHO IVB.

The main observations and recommendations are summarized below. Readers wishing to review the recommendations in full, and the rationale for each, should consult the numbered pages in Annex 8 referenced after each recommendation.)

### *Communications goals of ACs*

1. There is a need to clearly define the communications mission of IVB advisory committees. (*Annex 8 pages 58-59*).

#### *Key audiences*

2. There is a need to identify with precision the key audiences for all IVB AC communications, as described in Annex 8. The target audience of any particular AC will generally be a subset of the identified general audiences. (*Annex 8 pages 59-60*)

#### *Key themes and messages*

3. There is need to identify general themes and messages for IVB ACs communications. (*Annex 8 page 60*)

#### *AC communications planning*

4. It is recommended that ACs prepare annual communications plans as well as plans for major meetings and/or issues. These planning notes should be brief, follow a template, and identify the goals, objectives, target audiences and communications tactics for the communications work of that AC. (*Annex 8 page 61*)

#### *Transparency*

5. Agenda information on upcoming meetings of the major IVB ACs should be published as early as possible on the IVB public website. The practice of posting pre-meeting agenda information on a restricted password protected website for selected SAGE participants and observers (separate from the public site) is not consistent with the openness and transparency goals of the WHO, and should be reviewed. (*Annex 8 page 61*)
6. The transparency norm should be that information used to inform AC decisions, the formal records of AC deliberations, and the results of AC deliberations are considered public information unless there is a reason for non-disclosure. (*Annex 8 page 61*)

#### *Openness*

7. ACs may, at their discretion, use in-camera sessions to deal with matters where they feel confidentiality is required, while maintaining openness for all other proceedings. However, closed sessions and

private consultations should be the exception rather than the rule for ACs. (*Annex 8 page 62*)

8. Major ACs should identify, as part of their public report on proceedings, the nature of any confidential consultations undertaken in reviewing a matter, and the subject matter of – and rationale for – any in-camera sessions, and for any non-disclosed information. (*Annex 8 page 62*)

#### *Media relations*

9. AC Chairs/WHO technical staff should consult and work with WHO communication staff to develop an appropriate media relations approach for AC meetings reflecting the openness goals of the WHO. Communication staff should work with AC Chairs/technical staff – especially SAGE – to develop media relations tactics for meetings where media attention is expected, or sought. Routine media relations should include, at minimum, the issuance of news releases following key AC sessions, and conducting post-meeting interviews with selected media. (*Annex 8 page 63*)
10. Consideration should be given to holding SAGE and other major AC meetings in major international and regional media centres. In particular, effort should be made to host one annual SAGE meeting in regional centres. (*Annex 8 page 63*)

#### *Print versus electronic dissemination*

11. IVB HQ should work with regional offices to assess if and when there may be a need to disseminate AC reports in print format that are otherwise only available in electronic formats. Regional offices should work with HQ to ensure that this is done either directly by HQ, or by regional offices. (*Annex 8 page 64*)
12. The IVB unit should continue to improve its use of the web to showcase and disseminate information about the workings and advice of its major ACs. The IVB website should have a separate section for its advisory committees prominently linked from its top page. Using the GACVS site as a model, a template should be developed to create comprehensive subsites for each major AC. (*Annex 8 page 64*)

#### *Aligning HQ and Regional Communications on ACs*

13. A plan should be established allocating responsibility for AC communications between HQ and regional staff. It should cover the preparation of annual and meeting-specific communications plans, on-site communications support for major meetings, and post-event dissemination of information. (*Annex 8 page 65*)

*Evidence-based communications planning*

14. IVB HQ should undertake audience research to determine if the advice and recommendations from its ACs are reaching the targeted audiences and to determine if additional or alternative communications approaches or information products are needed to reach all regions. Baseline research should be established to assess communications effectiveness. (*Annex 8 page 66*)

*Inter-AC communications*

15. An orientation kit should be prepared for new AC members. It should include information needed to ensure that AC members understand the broad WHO context for their work, and in which their advice needs to be situated. In addition, all AC committees should be encouraged to use the WHO's secure online collaboration tool for creating, sharing, and storing information (i.e. Sharepoint) and to provide access to their information for members of other relevant ACs. (*Annex 8 page 66*)

-- End --

**ANNEXES TO REPORT ON REVIEW OF AC COMMITTEES.**

1. TOR AC review (*p.41*)
2. TOR Communication expert (*p. 46*)
3. List of external interviewees (*p. 47*)
4. Main documents reviewed by the Review Team (*p. 48*)
5. List of advisory committees with GIVS and IVB SP matrix (*p. 50*)
6. SAGE Terms of Reference (*p. 52*)
7. AC Budgetary Information (*p. 56*)
8. Communications assessment and recommendations (*p. 57*)
9. IVB and POL committees with responsible IVB focal points (*p. 67*)

## Annex 1

### Review of IVB advisory committees

#### Background

Over the past decade, the global immunization landscape has changed substantially. There are many more stakeholders in the vaccines and immunization arena than was previously the case. At the same time, the scope of immunization efforts has broadened, with the need to target other age groups (as outlined in the WHO/UNICEF Global Immunization Vision and Strategy (GIVS) 2006-2015), an increased number of new vaccines and technologies becoming available, and emphasis on provision of other critical health interventions (e.g. malaria control and nutrition) at immunization contacts.

WHO is the global body responsible for setting standards and formulating policies and recommendations for vaccines and immunization. Since the inception of the Expanded Programme on Immunization in the 1970s, WHO has been relying on committees of scientific and public health experts from across the world to contribute to the development of these policies.

The structure and operating mechanisms of existing WHO advisory committees for vaccines and immunization may no longer be appropriate to meet the challenges that arise from this new environment.

Over the years, with the broader scope of issues to be tackled at global, regional and country levels in the areas of standard-setting, vaccine development, and immunization, many specialized advisory committees have been established.

These committees have, however, gradually become independent from each other, leading to a loss of synergy and coherence in the formulation of policies and recommendations for use by countries and partners.

A recent WHO-wide external evaluation of the development process for policies and recommendations highlighted critical deficiencies, all of which apply to the development and acceptance of WHO's policies and recommendations on vaccines and immunization:

- insufficient links between committees, resulting in a lack of synergy and coherence in the formulation of policies and recommendations;
- insufficient preparation and management of advisory group meetings (lack of adequate resources); and
- over-emphasis on expert consensus (with debate often dominated by strong personalities and native English-speakers) as opposed to systematic review of available evidence and a formal process for policy/recommendation development.

WHO's current approach uses an ad hoc method to generate and disseminate policies and recommendations on vaccines and immunization.

Three main cross-cutting committees are involved in providing information to WHO in the policy/normative area: the Strategic Advisory Group of Experts (SAGE), which has recently been completely restructured in view of the above, the Expert Committee on Biologicals Standardization (ECBS), and the Global Advisory Committee on Vaccine Safety (GACVS). The function of these committees is shown

in Table 1. The Initiative for Vaccine Research Advisory Committee (IVAC), is also cross-cutting, but is not listed as it mostly focuses on priority-setting for vaccine research.

**Table 1**  
**The function of SAGE, ECBS, and GACVS**

<b>Committee</b>	<b>Function</b>	<b>Comments</b>
Strategic Advisory Group of Experts	To advise WHO on overall global policies and strategies on vaccines and immunization, ranging from vaccine and immunization technology research and development, to delivery of immunization and its linkages with other health interventions. The mandate of SAGE is not restricted to childhood vaccines and immunization but extends to all vaccine-preventable diseases.	Prior to its recent restructuring, SAGE operated in an ad hoc fashion as an advisory group to IVB, with a mandate and focus mostly limited to infant immunization and traditional Expanded Programme on Immunization vaccines. Its recommendations were of limited use to the global community. Other advisory groups without a clear relationship with SAGE proliferated in this unstructured environment. Following extensive internal and external consultations, and in view of the above, SAGE began operating under a new structure at the end of 2005, with an adjusted membership, membership selection process, ToRs, and modus operandi.
Expert Committee on Biological Standardization	To establish detailed technical specifications (called recommendations and guidelines) for the regulation, manufacture, and quality control of vaccines, blood products, other biological medicines and related in vitro diagnostic tests.	Conclusions and recommendations should be a component of the evidence base used by SAGE to advise WHO. Standards are required to guide production and regulation of vaccines. Standards need to be met in order for a vaccine to be pre-qualified by WHO for supply through UN agencies.
Global Advisory Committee on Vaccine Safety	To advise WHO on vaccine safety issues of potential global importance.	Conclusions and recommendations should be a component of the evidence base used by SAGE to advise WHO on policy.

Additional committees also provide information to SAGE or GACVS on an informal basis. These committees have no clear process or mandate for moving this information to the appropriate decision-making groups. Table 2 shows a list of those committees based at WHO HQ IVB which are involved in vaccines and immunization. Information is provided to the ECBS by ad hoc consultations of subject experts. These consultations are convened on the basis of the priority topics identified for consideration by the ECBS.

**Table 2**  
**WHO HQ-based committees involved in vaccines and immunization, as of the end of 2004**

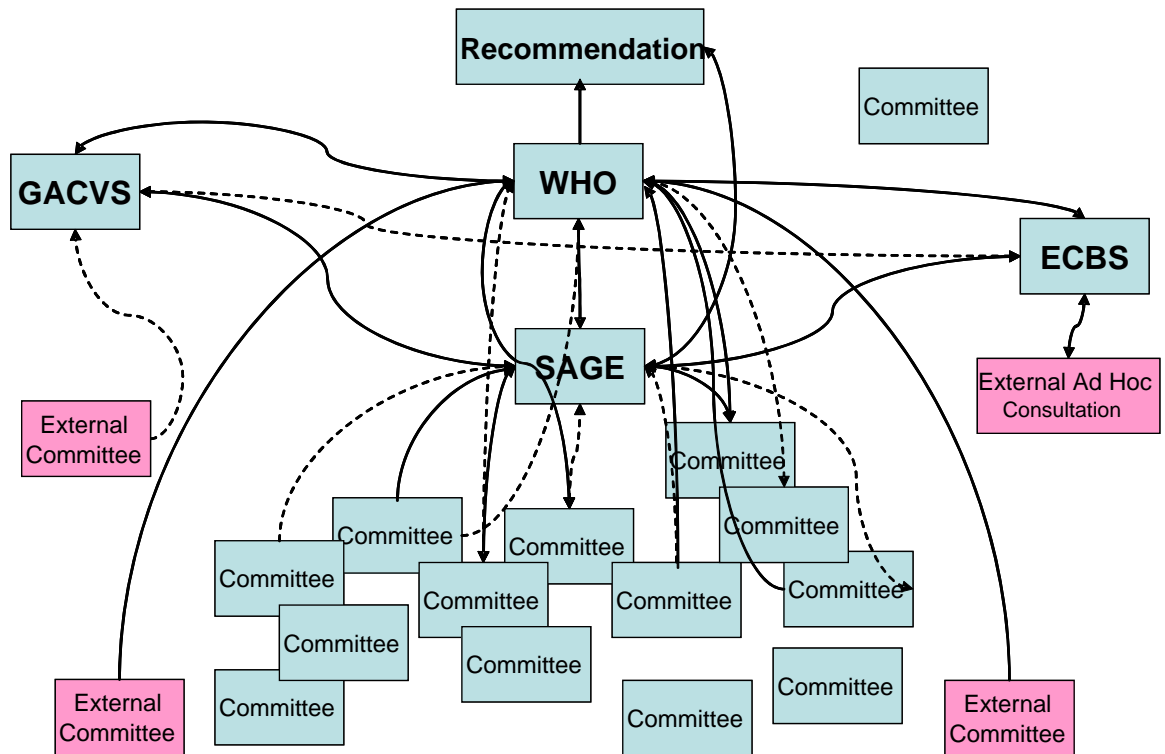
- Initiative for Vaccine Research Advisory Committee
- Malaria Vaccine Advisory Committee
- Steering Committee on Diarrhoeal Disease Vaccines
- Steering Committee on New Vaccine Delivery Systems
- WHO Product Development Group for the Measles Aerosol Project
- TB Vaccine Steering Committee
- HVI Management Support Committee
- WHO-UNAIDS AIDS Vaccine Advisory Committee
- Steering Committee of the African AIDS Vaccine Program
- Steering Committee on Dengue and other Flaviviruses Vaccines
- Steering Committee on Research Related to Measles and Rubella Vaccines
- Vaccination Steering Committee on Epidemiology and Field Research
- Trivalent Vaccine Clinical Task Force
- Meningitis Vaccine Project Advisory Group
- Global Advisory Committee on Vaccine Safety
- Expert Committee on Biological Standardization
- Ad Hoc Expert Committee on Vaccine Prequalification
- Steering Committee on Immunization Safety
- Strategic Advisory Group of Experts
- Technet
- Immunization Training Partnership
- Advisory Committee on Training
- Advisory Committee on Estimates of Vaccine-Preventable Diseases
- Global Commission for the Certification of the Eradication of Poliomyelitis
- Global Polio Management Team
- Steering Committee for Research on Post-Certification Policy for Poliomyelitis

Figure 1 provides a schematic of the current flow of information as it is passed from one group to another before WHO policies and recommendations are produced. It shows the presence of multiple paths, tenuous or lack of linkages, multiple sources of information feeding multiple destinations, redundancies, and little coordination.

**Figure 1**

**Schematic of current information flow**

This schematic is a representation of the general relationship between various committees (both internal and external to WHO) and WHO leadership. Links between internal committees (both internal and external to IVB) are informal and ad hoc.



As part of an attempt to strengthen the WHO's current committee structure, it is expected that a well-defined path of information flow with clear linkages will be established.

**Terms of reference**

- Conduct a thorough review of the scope and roles of existing advisory committees for vaccines and immunization, particularly those internal to WHO at HQ and regional levels, and with due consideration to key advisory groups from partner organizations.

The review should also consider other committees and structures not specific to immunization but which may at times issue recommendations with direct or indirect bearing on immunization.

- Review of relevance and roles of IVB committees in the context of the GIVS, restructured SAGE, core functions of WHO and partners and how they feed into SAGE and policy making.

- Provide recommendations to adjust the structure of existing WHO IVB committees, their composition, and terms of reference to achieve the alignment, linkages, and integration needed for a coherent foundation for SAGE's and other policy making activities. This should take into consideration the various potential categories of advisory committees (strategic, managerial, policy setting, technical..). The recommendations should be consistent with WHO's rules about expert and scientific advisory committees.

The expected output is a report to be available in draft by end of December 2006 and to be presented and discussed at the April 2007 SAGE meeting.

### **Proposed process**

#### 1. Review of committees' ToRs and composition

- The secretariat will provide the review team with an updated list of IVB and regional advisory groups with current membership, terms of reference, and sets of previous reports and recommendations.

#### 2. Consultation

- Interview with the Chairpersons and focal points for these advisory groups and, at the discretion of the review team, an additional number of advisory group members and members of the secretariat
- Interview of key partner organizations (through official representatives) and key informants

#### 3. Drafting of a proposal and recommendations on needed adjustments to the committee structure and linkages between the various committees.

## **Annex 2**

# **Consultancy on Communications**

### **Background**

The Department of Immunization, Vaccines and Biologicals (IVB), at WHO HQ is organizing a review of the advisory committees of IVB. The review will be conducted by an external committee headed by Bjorn Melgaard. The team is expected to produce a final report by end December 2006. TORs for the review are attached as Annex 1.

The need for communications expertise to advise the committee has been recognized; IVB is therefore looking for a communications expert to provide assistance.

The consultancy is expected to be of 3 weeks duration and should preferably be conducted during the period 9 October - 30 October.

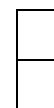
The objective of the consultancy is:

- To provide advice to the review committee on how to increase the penetration and impact of reports and recommendations from the IVB advisory committees to key target audiences.
- To provide advice to the review committee regarding any possible contribution that enhanced communication could make to improving synergy and coherence among and between various committees

The output should be a short paper with recommendations to IVB. If feasible it should be formatted in such a way that it can be incorporated in the report of the review committee.

The consultant should be a communications expert with knowledge about WHO and its working methods.

8 September 2006



## LIST OF EXTERNAL INTERVIEWEES

NAME	DESIGNATION	DATE
Paul Henri Lambert	Professor of Vaccinology. University of Geneva	03.09.06
Steve Landry	Senior Adviser, Gates Foundation	16.10.06
Steve Cochi	Senior Adviser, CDC	23.10.06
Peet Tull	Senior Expert, ECDC	24.10.06
Mira Kojouharova	Nat. Consultant on Epidemiology, Sofia Bulgaria	23.10.06
Patrick Olin	Professor of vaccinology and vaccine Research. University of Stockholm	24.10.06
David Salisbury	National Programme Manager, UK	30.09.06
Stephen Inglis	Director, NIBSC, UK	29.09.06
James Cheyne	Associate Director, PATH, Ferney	11.10.06
Michel Zaffran	Dep. Executive Secretary, GAVY	10.10.06
Shanelle Hall with Thomas Sorensen	Director UNICEF Supply Division and Chief of Vaccines	31.10.06
Mark Miller	Ass Director Fogarty programme, NIH	09.11.06
Amie Batson	Focal point on Immunization, World Ban	07.11.06
Jon Andrus	Senior Adviser on Immunizations, PAHO	07.11.06
Ciro de Quadros	President Sabin Vaccine Institute	07.11.06
Anne Schuchat with Melinda Wharton	Director and Deputy Director National Center for Immunization and respiratory Diseases, CDC	08.11.06
Brent Burkholder with Bob Keegan, Vance Dietz and Denise Johnson	Ag Director, Global Immunization Divison CDC	08.11.06
Alan Court	Programme Director, Unicef NY	15.11.06
S. Jadav	Executive Director, Serum Institute of India	21.11.06
Michel Greco	Independent Consultant	21.11.06
Muhammad Ali Jaffer	Senior Adviser MOH Oman	21.11.06
Salah Al-Awaidy	Director, MOH Oman	21.11.06
Elaine Esber	Executive Director Merck	22.11.06
Ryoko Krause	Director IFPMA	22.11.06
Robert Steinglass	Director BASICS	22.11.06
Barbro Carlsson	Head, SIDA Resaech Division	29.11.06
Paul Fife	Director, NORAD Health Section	01.12.06

## Annex 4

### **DOCUMENTS CONSIDERED BY THE REVIEW COMMITTEE**

The following documents were considered by the review committee in the conduct of its work:

1. Immunization, Vaccines and Biologicals: Strategic Plan 2006-2009 (2005) – WHO/IVB/o5.22.
2. GIVS: Global Immunization Vision and Strategy (WHO, 2005).
3. Strategic Advisory Group of Experts (SAGE): Terms of Reference, 12 September 2005.
4. Director's Office 2006-2007 Structure (1<sup>st</sup> October 2006).
5. WHO Headquarters Structure (1<sup>st</sup> February 2006).
6. IVB and POL committees with corresponding IVB focal points (undated).
7. Other HQ non IVB/POL committees and non WHO advisory committees with bearing on immunization (internal document, undated).
8. Governance scenarios for research in WHO: A foundation for the WHO research strategy. T. Pang, R. Ridley, M-P Kieny and P Van Look. Power Point presentation, undated.
9. Listing of IVB meetings, 2006.
10. Review of IVB Policies – draft (October 2006). Laura McDougall and David Strong.
11. WHO Collaborating Centres – networks (2006).
12. WHO Collaborating Centres – fact sheet (2006).

13. WHO Expert Advisory Panels and Committees (2006). WHO Basic Documents
14. The use of evidence in WHO recommendations (2004). A. Oxman, J. Lavis, A. Fretheim.
15. Terms of reference of committees of IVB, including regional technical committees. IVB inventory (Undated)
16. SAGE November 2006. "Yellow Book". Department of IVB 2006
17. Eleventh General Programme of Work, WHO 2006

Annex 5:

AC List With GIVs and IVB SP Matrix

Advisory Committees		GIVS				IVB SP		
		Protecting more people	New vaccines and	Integrate Immunization	Global Interdependence	Innovation	Quality and safety	Improved access
1	Initiative for Vaccine Research Advisory Committee		X			X		
2	Malaria Vaccine Advisory Committee		X			X		
3	Steering Committee on Diarrhoeal Disease Vaccines		X			X		
4	Steering Committee on New Vaccine Delivery Systems		X			X		
5	WHO Product Development Group for the measles Aerosol Project		X			X		
6	TB Vaccine Steering Committee		X			X		
7	WHO-UNAIDS AIDS Vaccine Advisory Committee		X			X		
8	Steering Committee of the African AIDS Vaccine Program		X			X		
9	Steering Committee on Dengue and other Flaviviruses Vaccine		X			X		
10	Steering Committee on Research related to Measles and Rubella Vaccines		X					
11	Advisory Committee on Intermittent Preventive Treatment of infants and EPI			X		X		X

Advisory Committees		GIVS				IVB SP		
		Protecting more people	New vaccines and	Integrate Immunization	Global Interdependence	Innovation	Quality and safety	Improved access
	serology							
12	Global Advisory Committee on Vaccines Safety	X					X	
13	Expert Committee on Biological Standardization	X					X	
14	Ad Hoc Expert Committee on Vaccine Prequalification (Proposed)	X						X
15	Ad Hoc Committee on NRA Assessments (Proposed)	X						X
16	Strategic Advisory group of Experts	X	X	X	X	X	X	X
17	Technet (Forum)	X	X				X	
18	HPV expert advisory group		X			X		
19	Immunization Training Partnership (Forum)	X		X			X	
20	Advisory Committee on Training	X		X		X		X
21	Performance Quality and Safety steering committee (Internal WG)	X					X	
22	Advisory Committee on Estimates of Vaccine-Preventable Diseases	X		X				X
23	Global Commission for the Certification of the Eradication of Poliomyelitis	X						X
24	Advisory committee on polio eradication	X		X				X

## **Annex 6**

### **Strategic Advisory Group of Experts (SAGE) Terms of reference, 12 September 2005**

#### **Functions**

SAGE is the principal advisory group to the World Health Organization (WHO) for vaccines and immunization. SAGE is charged with advising WHO on overall global policies and strategies, ranging from vaccine and technology research and development, to delivery of immunization and its linkages with other health interventions. The mandate of SAGE is to provide strategic advice rather than technical input. It is not restricted to childhood vaccines and immunization but extends to all vaccine-preventable diseases.

SAGE will specifically advise the WHO Director-General on the:

1. adequacy of progress towards the achievement of the goals of the Global Immunization Vision and Strategy (GIVS);
2. major issues and challenges to be addressed with respect to achieving the goals of GIVS;
3. immunization response to current public health priorities;
4. major general policies, goals and targets including on vaccine development and research;
5. adequacy of WHO's strategic plan and priority activities to achieve the GIVS goals consistent with its mandate and considering the comparative advantages and the respective roles of partner organizations;
6. cross-departmental activities and initiatives related to vaccine and immunization technologies and strategies and linkages with other health interventions;
7. engagement of WHO in global immunization-related partnerships.

#### **Membership**

SAGE shall have 15 members, who shall serve in their personal capacity and represent a broad range of disciplines covering immunization activities.

SAGE members are acknowledged experts from around the world in the fields of epidemiology, public health, paediatrics, vaccinology, infectious diseases, immunology, drug regulation, management, immunization delivery, health-care administration, health economics, and vaccine safety.

The membership of SAGE shall seek to reflect a representation of:

- (1) professional affiliation (i.e. academia, medical profession, research institutes, and governmental bodies including national immunization programmes, public health departments and regulatory authorities);
- (2) major areas of interest (e.g. influenza control, diarrhoeal diseases, respiratory diseases, research, biologics, and safety); and
- (3) the three major strategic areas of WHO's work relating to immunization (i.e. accelerating innovation, ensuring quality and safety, and maximizing access and links with other health interventions).

SAGE members, including the Chairperson, shall be nominated by the WHO IVB Director in consultation with WHO Regional Offices and other relevant WHO departments. Notwithstanding the foregoing, all new SAGE nominations as well as renewals and discontinuation of appointments to SAGE will be approved by the WHO Director-General. Members will be appointed by the WHO Director-General. Consideration will be given to ensuring appropriate geographic representation and gender balance.

Members of SAGE, including the Chairperson, shall be appointed to serve for an initial term of three years. Such three-year term may only be renewed once. Prior to being appointed as SAGE members and prior to renewal of term, nominees and current SAGE members shall be required to complete a WHO declaration of interest as per the attached form.

In addition, SAGE nominees shall be required to sign confidentiality agreements prior to confirmation by WHO of their appointment as SAGE members (see Annex 2). All papers presented to SAGE, which may include pre-publication copies of research reports, or documents of commercial significance, shall be treated as confidential.

SAGE deliberations are confidential and may not be publicly disclosed by SAGE members.

A register of members' interests and signed confidentiality agreements shall be maintained by WHO.

Membership in SAGE may be terminated for any of the following reasons:

- (1) failure to attend two consecutive SAGE meetings;
- (2) change in affiliation resulting in a conflict of interest; and
- (3) a lack of professionalism involving, for example, a breach of confidentiality.

### **Roles and responsibilities of SAGE members**

Members of SAGE have a responsibility to provide WHO with high quality, well considered, advice and recommendations on matters described in the

SAGE terms of reference. Members play a critical role in ensuring the reputation of SAGE as an internationally-recognized advisory group in the field of immunization. They will be committed to the development and improvement of public health policies.

SAGE's focus will be to provide strategic advice rather than technical input. Focused technical input will be solicited from other expert/advisory scientific groups.

The Committee has no executive function. Its role is purely to provide advice and recommendations to the Director-General of WHO. This includes providing advice and recommendations on urgent matters as needed.

SAGE members may be approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of SAGE. SAGE members shall refer such enquiries to WHO.

### **Meetings and operational procedures**

SAGE will normally meet twice a year. The frequency of meetings may, however, be adjusted as necessary. Decisions or recommendations will, as a rule, be taken by consensus.

UNICEF, the Secretariat of the Global Alliance for Vaccines and Immunization (GAVI), and WHO Regional Offices will participate in SAGE meetings and deliberations as observers.

WHO may also invite representatives from WHO regional technical advisory groups, non-governmental organizations (NGO), international professional organizations, technical agencies, donor organizations and associations of manufacturers of vaccines and immunization technologies as observers to SAGE meetings.

Additional experts may be invited to meetings as appropriate to further contribute to specific agenda items.

SAGE will work with WHO to develop its priorities of work and meeting agendas through an agenda setting sub-group. This sub-group shall be comprised of the chairperson and two additional SAGE members identified jointly by the Chair of SAGE and the secretariat.

SAGE will be kept informed by WHO and partner agencies of progress in implementation of strategies and the attainment of objectives at country and regional level. SAGE will also be informed of policies and recommendations set by the WHO regional technical advisory groups. WHO, with advice from SAGE, will determine what policy issues and information from other WHO technical advisory/steering groups should be brought to the attention of SAGE.

SAGE may appoint SAGE sub-working groups to follow-up and liaise with the WHO secretariat on specific work items and/or recommendations that will subsequently be submitted to the full group for consideration. The function of such sub-working groups will be time-limited. The SAGE chairperson, in consultation with WHO, will identify the need for such sub-working groups and recruit SAGE members to serve on them. WHO staff will be identified as lead staff to work with the chair of such sub-working groups and to recruit additional members and additional experts as appropriate. Sub-working groups shall determine the most efficient manner for accomplishing their work.

In addition to attendance of meetings, SAGE participation will be expected from all members throughout the year, including participation in sub-working groups, video and telephone conferences as well as interactions via email. Review of documents may also be solicited.

SAGE members will not be remunerated for their participation in SAGE, however, reasonable expenses such as travel expenses will be compensated by WHO.

SAGE members may be requested to participate as observers in other important WHO departmental or cross-departmental meetings.

SAGE reports to the WHO Director-General or his designee(s). The SAGE chairperson will debrief the Director-General or his designee, and the IVB Director, following each SAGE meeting. Minutes of SAGE meetings will be taken and circulated among SAGE members.

The recommendations/conclusions of SAGE meeting shall be published, with the prior approval of WHO, in the Weekly Epidemiological Record, and posted on the IVB Departmental website within two months of each SAGE meeting.

## Annex 7 – AC Budgetary Information

Annex budget

Team	0	Planned Cost 2006	Planned Cost 2007	Total Planned Cost 2006-2007
IVR	Initiative for Vaccine Research Advisory Committee		90.000	90.000
	Malaria Vaccine Advisory Committee	100.000	90.000	190.000
	Steering Committee on Diarrhoeal Disease Vaccines	90.000	90.000	180.000
	Steering Committee on New Vaccine Delivery Systems	90.000	90.000	180.000
	WHO Product Development Group for the Measles Aerosol Project	90.000	90.000	180.000
	TB Vaccine Steering Committee	90.000	90.000	180.000
	WHO-UNAIDS AIDS Vaccine Advisory Committee	90.000	90.000	180.000
	Steering Committee of the African AIDS Vaccine Program	90.000	90.000	180.000
	Steering Committee on Dengue and other Flaviviruses Vaccines	90.000	90.000	180.000
	Steering Committee on Research Related to Measles and Rubella Vaccines			-
	HPV expert advisory group	60.000	60.000	120.000
	Advisory Committee on Estimates of Vaccine-Preventable Diseases <i>(note name will change)</i>			90.000
EPI+	Technet	95.000	95.000	190.000
	Immunization Training Partnership		40.000	40.000
QSS	Expert Committee on Biological Standardization	165.000	165.000	330.000
	Ad Hoc Expert Committee on Vaccine Prequalification	-	-	-
	Ad Hoc Committee on NRA Assessments	-	-	-
	Advisory Committee on Training		70.000	70.000
	Global Advisory Committee on Vaccine Safety	210.000	210.000	420.000
	PQS steering committee	-	-	-
DO	Strategic Advisory Group of Experts	210.000	210.000	420.000
<b>TOTAL</b>		<b>1.470.000</b>	<b>1.540.000</b>	<b>2.800.000</b>

based on actual 2006 cost

No meeting in 2006, as fa

no budget needed

no budget needed

no budget needed

## Annex 8

### **Assessment and Recommendations Regarding Communications for WHO Advisory Committees On Immunization and Vaccines Matters**

**Prepared By Peter O'Malley  
For the Review Team Examining  
IVB Advisory Committees**

This report contains observations and recommendations to enhance the communications practices and effectiveness of major advisory bodies to the WHO on matters related to immunization and vaccination.

It is based on information obtained through meetings and interviews conducted in Geneva the week of October 9, 2006, subsequent telephone interviews, and a review of various internal and external documents relevant to WHO communications and the operations of the advisory committees (ACs).

This report has been prepared as a contribution to an overall review of the efficacy of advisory groups being conducted for the WHO Immunization, Vaccine and Biologicals Department (IVB) by a panel of external consultants.

#### Scope

This note focuses principally on the communications activities of the three major advisory bodies to the IVB department -- SAGE, ECBS and GACVS.

Except where otherwise noted, the 20-plus ad hoc and other advisory entities currently associated with the department's work are not discussed here in any detail.

Similarly, except where noted, this report does not examine in detail the communications practices of regional technical ACs that advise WHO regions on immunization and vaccine matters.

#### Strategic assessment

- Since the acceptance and actioning of advice from WHO ACs is highly dependent on the credibility of that advice, the WHO endeavors to ensure that ACs are comprised of top scientific experts in the public health areas under consideration, and that decisions are made based upon the best available science. Given the resulting high level of credibility of these ACs, few public health authorities – including WHO program officials – are prepared to be off-side with WHO AC policy advice and protocols. In consequence, these major ACs are, in many ways, more accurately understood as decision-making bodies rather

than as mere advisory instruments.

- The WHO does not routinely undertake research into whether its dissemination activities, and those of its ACs, are effectively reaching the right target audiences. Based on the limited research undertaken to prepare this report, there is no persuasive anecdotal evidence, however, indicating that public health authorities and practitioners who need to know, and should know about the advice of WHO ACs, are not getting the information they need. For the most part, it seems that those who need to know about AC advice generally find out about it through formal or informal professional channels at the HQ, regional and country levels. Accordingly, from the standpoint of getting the right information to the right actors, there is no compelling evidence suggesting a need to significantly change communications activities from WHO ACs.
- It is also true, however, that the WHO is committed to transparency in its deliberations and decision-making. Since ACs play a key role in this process, it follows that the deliberations of ACs need to be as transparent as possible. At present, however, the work agendas and deliberations of IVB ACs generally have very limited visibility outside (and even within) the relatively small professional community attentive to immunization matters. Even in the case of the major IBV ACs, the visibility of their deliberations is generally limited to direct and indirect participants, and others who are part of the professional and business networks with direct interests in the subject. In the case of less-prominent ACs, awareness of their work and their advice is more limited still. There is, in consequence, a rationale for enhancing AC communications to improve the transparency of AC operations to create improved awareness of the work and activities of ACs and of the issues being addressed by ACs among all stakeholders with an interest in these programs..
- Similarly, the WHO has a strategic interest in promoting global awareness of the importance of immunization, and of the progress being made by the WHO and its partners in combating disease through immunization. While this outreach task is principally the work of the WHO IVB department itself, the deliberations and activities of its ACs provide an ongoing opportunity for promoting awareness and interest in this area of public health. In this regard, there is more than could be done to take advantage of the communications and outreach opportunities associated with the work of the major ACs to IVB.

### Defining the communications mission of IVB ACs

Based on research conducted for this report, and given the above context, the defined communications strategy of IVB advisory committees should be to communicate in manner that will:

- Ensure that public health authorities, policy makers and key public health implementers in member states, immunization program donors, civil society and industry are aware of the advice emanating from IVB ACs, and are encouraged to comply with the policies, protocols and other advice recommended by the AC;
- Ensure that public health authorities and practitioners with an interest in matters under consideration by IVB ACs are aware of the issues and matters under consideration in an open and timely manner, and have an opportunity to follow and offer input into these deliberations, when and as appropriate; and
- To communicate with media and broader public health and public audiences, as possible, so as to promote acceptance and awareness of the importance of immunization, and of the progress made in the control of disease through global immunization programs.

***Recommendation 1:***

***That IVB ACs adopt the above set of goals to guide in planning and implementing their communications activities.***

Recommended key audiences

The key stakeholders and audiences for IVB AC communications are as follows:

- Political and policy decision-makers in member states who are responsible for implementing the advice of IVB ACs;
- Health authorities and regulators who participate in or influence health decision-making on these matters in member states;
- Regional WHO TAG members and WHO program officials responsible for promoting implementation of WHO immunization policies and standards in member states need to know about AC advice and processes;
- International partner organizations and donor organizations that are involved in and/or fund immunization programs;
- Public health and technical professionals in member states who are responsible for implementing immunization programs;
- Manufacturers of vaccines, as well as manufacturers of equipment and devices used in immunization programs;

- Specialized media who report on public health issues, and in particular on issues and development related to immunization and vaccine initiatives;
- Other public health and public stakeholders in member states who may have interest in matters under consideration by IVB ACs

***Recommendation 2:***

***That WHO advisory committees on immunization and vaccine related matters target their communications at the audiences identified above.***

Key themes and messages

In communicating their advice to stakeholders and key audiences, IVB advisory committees should integrate the following general themes and messages into their communications:

- That their advice has been developed by top experts in the field using the best scientific evidence and an appropriate investigative and analytical methodology;
- That their specific advice will promote one or more of the strategies articulated in GIVS, which calls on WHO and member states:
  - to protect more people from vaccine-preventable disease;
  - to develop new vaccines and technologies;
  - to integrate immunization into other health interventions; and
  - to implement immunization programs in the context of global interdependence.
- That their advice has been developed, and is offered to member states, in an open and a transparent manner.

***Recommendation 3:***

***That the above themes be incorporated into communications products disseminated by WHO advisory committees working on immunization and vaccination matters.***

Communications Planning Processes

IVB ACs do not currently prepare regular or event-specific communications plans to guide their dissemination, communications and outreach activities. It

is recommended that ACs do this at least annually, and also prepare brief communications plans for all major sessions of the major ACs.

These planning notes should follow a template and identify:

- *The strategic communications goals* of the AC for the upcoming year, and/or for particular sessions;
- *Communications objectives around particular issues and meetings* that are expected to be addressed in the planning timeframe;
- *Key audiences and key messages* for AC communications around key issues and meetings, and around anticipated key decisions and advice;
- The proposed *dissemination and communications tactics* to be adopted to promote awareness of the deliberations of the AC, and to disseminate information about its recommendations.

***Recommendation 4:***

***That ACs prepare annual communications plans, as well as plans for key issues and events, as described above. This communications planning activity should be made part of the routine financial and program planning process done by and for ACs within WHO.***

Communications around AC meetings

*Transparency*

***Recommendation 5***

***Agenda information on meetings of the major IVB ACs should be published as early as possible on the IVB public website. The use of a private, password protected website exclusively for selected SAGE participants and observers should be reviewed as to its consistency with the openness and transparency goals of the WHO.***

All reports, studies and presentations used to inform deliberations at AC meetings should be considered public information unless there is reason to maintain its confidentiality. Information that is held as confidential should be listed on the AC website, along with a statement indicating why it is deemed to be confidential.

***Recommendation 6***

***The transparency norm should be that information used to inform AC decisions, the formal record of AC deliberations, and the results of AC deliberations should be considered public information, unless there is a***

***reason for non-disclosure.***

*Openness*

Meetings of major IVB ACs are currently open to observers, though observers are required to sign a declaration agreeing to keep all information discussed and statements made at meetings confidential. This practice is awkward at best, and not fully consistent with the transparency and openness goals of the WHO, or with standards currently observed by many governments.

***Recommendation 7***

***Efforts should be made to allow for less restricted access to meetings. ACs can, at their discretion, use in-camera sessions to deal with matters where they feel confidentiality is required, and maintain openness for all other proceedings. The chairs and members of an AC can also conduct confidential consultations with any groups, where they feel the need. However, closed sessions and private consultations should be the exception rather than the rule.***

***Recommendation 8***

***Major ACs should be required to identify, as part of their public report on proceedings, the nature of any confidential consultations undertaken in reviewing a matter, and the subject matter of – and rationale for – any in-camera sessions, and for any non-disclosed information.***

*Media relations*

To date it has not been the practice of WHO to promote coverage of the work of IVB ACs via news media. This is due to several factors:

- Because of the technical nature of much of the AC work, WHO communicators have generally concluded (correctly) that little of what happens at most AC meetings would be of interest to news media.
- In some cases, it is thought to be counter-productive to have some issues dealt with in a high-visibility manner.
- As well, as noted earlier, the background evidence used to inform AC recommendations is not always public, nor are the meetings themselves fully open, so it can be problematic generating and managing media interest in closed-door proceedings.
- SAGE meetings are always held in Geneva which is not a media centre, and where it is difficult to attract media attention.

In this regard, it is noteworthy that some regional Technical Advisory Groups have made significant strides in promoting and opening up their deliberative processes to media, with considerable success.

PAHO in particular prepares communications plans for each of its TAG meetings, and makes an effort to attract media to these meetings. PAHO also holds its TAG meetings in different parts of the region to attract media attention, particularly on issues of regional importance.

As noted above, SAGE meetings are now officially open to the public, including members of the media. This openness raises the prospect that media will eventually at some future point choose to attend SAGE sessions either as a result of their own journalistic interests, or at the urging of some party who wants to promote media interest in some issue being dealt with by SAGE.

There is also the possibility that issue-advocates may target future SAGE meetings to generate publicity around their issues. This possibility increases to the degree to which SAGE becomes the recognized WHO “umbrella” AC on immunization and vaccination issues.

***Recommendation 9:***

***Given that AC meetings provide an opportunity to generate media coverage around immunization issues, and in light of the possibility that issue advocates and/or news media themselves may choose to attend and report on AC proceedings that are now open to the public, ACs should consult and work with WHO communicators to develop an appropriate media relations approach and policy that reflects the new openness.***

***WHO communicators should also work with ACs to develop media relations tactics for meetings where media attention is expected, or sought. This should include, at minimum, the issuance of news releases following key AC sessions, and conducting post-meeting interviews with selected media.***

***Recommendation 10***

***Consideration should be given to holding SAGE and other major AC meetings outside of Geneva in major international and regional media centres. In particular, effort should be made to host one of the two annual SAGE meetings in different regional centers.***

***Dissemination***

At present, dissemination of AC advice from the three major IVB expert advisory committees takes place principally via meeting reports published in the *Weekly Epidemiological Record (WER)*. They are also reported in the IVB’s “Global Immunization News”. The *WER* reports provide summaries of AC recommendations on key topics, as well as summaries of the evidence upon which AC advice is based. Discerning readers can also identify future issues being dealt with by an AC, and other updated information, in the text of

these reports.

The previously-printed and surface-mailed *WER* publication is now produced and distributed in electronic format only. It is posted weekly on the WHO website, and also emailed directly to a list of email subscribers.

As noted earlier, it is not evident that there is any major flaw in this dissemination strategy, at least in terms of reaching the professional audiences that need to get this information. Accessing this information electronically is likely the preferred method – or at minimum is acceptable – for much of the target audience in the developed world. In the developing world, however, where the prevalence of information technology is less pronounced, electronic dissemination may not be sufficient to reach the target audience.

***Recommendation 11:***

***That IVB HQ work with regional offices to assess if and where there may be a need to disseminate information in print format to officials and practitioners in particular member states. In cases where there is a need for enhanced physical dissemination of AC materials in particular countries, HQ should work out a protocol with regional offices to ensure that this is done either directly by HQ, or by regional offices on behalf of the WHO.***

AC meeting reports in the *WER* are highly technical, and not particularly easy to read or to scan, nor are the topics covered in these reports indexed for reference. As well, these reports do not provide detailed citations about the reports, studies and evidence used to inform particular recommendations. In consequence, while these reports give readers notice of major decisions and recommendations, they may not be well designed to meet fully the needs of either specialists in the field, or non-technical persons or policy-makers with a general interest in this area of public health.

***Recommendation 12:***

***The IVB department should continue to improve its use of the web to showcase and disseminate information about the workings and advice of its major advisory committees. In particular, the IVB website should have a separate section for its advisory committees prominently linked from its top page. Using the GACVS site within the IVB site as a starting point, a template should be created to guide in creating comprehensive subsites for each major advisory committee. Each subsite should include information of the AC's terms of reference, its nomination procedures, its current membership, meeting reports, any special reports, agendas for upcoming meetings, and indexed information about specific topics on which advice and positions have been offered.***

Other Issues and recommendations

## *HQ and Regional Communications*

Interviews with a small number of WHO HQ and regional communications staff suggest there is often a significant disconnect between what is happening with HQ and in the regional communications. Frequently, if not usually, neither knows what the other is up to. This appears to be a WHO-wide organizational (and perhaps cultural) problem, and not specific to the IVB area.

### ***Recommendation 13***

***In the case of communications from IVB ACs, a protocol should be established that would allocate responsibility for communications from ACs as follows:***

- ***HQ communicators supports HQ ACs in preparing annual and event-specific dissemination and communications plans;***
- ***HQ communications provides media relations and communications support to HQ ACs during public meetings; and***
- ***AC post-meeting dissemination and communications activities and information distributions should be designed on the premise that WHO regional offices are the principal communications channels to member states and to regional stakeholders, and that the relevant role of HQ communications is to support regional offices in meeting their communications responsibilities.***

### *Audience research*

Based on interviews with WHO communications staff, WHO communications strategies and tactics are not generally informed by research on audience and stakeholder requirements and preferences, nor are the results of these initiatives measured using audience research.

Given this, it is not surprising that there has not been any systematic effort to determine the degree to which reports and other information from the IVB ACs are actually reaching the intended target audiences. A survey on the impact of IVB publications was prepared and conducted in 2006 for use at a training conference, and while the results are interesting, the sample of respondents from this single session is too small to make any broad conclusions.

Similarly, while it is possible to extract from web server logs information about overall traffic to the IVB web site and to the online *WER*, it is not possible to use this data to determine the exact identify of site visitors, and the degree to which target audiences are represented in this traffic. Consequently, there is currently no evidence base on which to surmise whether information from the ACs is – or is not – reaching the targeted audiences. Nor is there an evidence base to understand the impact on key audiences of moving from print to

online dissemination practices.

**Recommendation 14:**

***IVB HQ should undertake audience research to determine if the advice and recommendations from its advisory committees is reaching the targeted audiences, to assess the effectiveness of its current dissemination practices, and to determine if additional or alternative communications approaches or information products are needed to reach target audiences in all regions more effectively.***

*Inter- AC Communications*

It was noted in meetings and interviews that new AC members are frequently not well informed about WHO, and hence have difficulty formulating advice that reflects the values and goals of the organization. It was also noted that there is often a lack of knowledge by experts involved in a particular advisory committee activity about what may be happening in other ACs who may be examining closely-related issues.

**Recommendation 15:**

***An orientation kit should be prepared for new AC members. It could include information needed to ensure that AC members understand the broad WHO context in which their work takes place, and the context in which their advice needs to be situated.***

***As well, all AC committees should begin to use the WHO's secure online tool for creating, sharing, and storing information (i.e. Sharepoint). Each AC should have its own Sharepoint site. To ensure information-sharing across ACs, all AC members should be able to access not just their own AC Sharepoint sites, but also be able to access most materials on the Sharepoint sites of other ACs.***

-- end --

## Annex 9

### IVB and POL committees with responsible IVB focal points

R&D	Initiative for Vaccine Research Advisory Committee MPK
R&D	Malaria Vaccine Advisory Committee ZR
R&D	Steering Committee on Diarrhoeal Disease Vaccines DS
R&D	Steering Committee on New Vaccine Delivery Systems MF
R&D Time bound	WHO Product Development Group for the Measles Aerosol Project AMH
R&D	TB Vaccine Steering Committee UF
R&D	WHO-UNAIDS AIDS Vaccine Advisory Committee SO
R&D	Steering Committee of the African AIDS Vaccine Program CT
R&D	Steering Committee on Dengue and other Flaviviruses Vaccines JH
R&D	Advisory Committee on Estimates of Vaccine-Preventable Diseases LW
R&D	HPV expert advisory group FC
R&D Time bound	Advisory committee on IPTi and EPI serology TG
R&D	Advisory Committee on Estimates of Vaccine-Preventable Diseases LW
Immunization Standards	Global Advisory Committee on Vaccine Safety PD
Immunization - not established	Expert Committee on Biological Standardization DW
Immunization - not established	Ad Hoc Expert Committee on Vaccine Prequalification ND
Cross cutting Forum	Ad Hoc Committee on NRA Assessments ND
Forum	Strategic Advisory Group of Experts PD
Immunization	Technet JB
	Immunization Training Partnership JB
	Advisory Committee on Training UK
Internal WG	PQS steering committee UK
Independent Commission	Global Commission for the Certification of the Eradication of Poliomyelitis RT
Immunization	Advisory committee on polio eradication RT