

Management Response

Evaluation Title	Evaluation of the Strategic Advisory Group of Experts (SAGE) on Immunization
Commissioning Unit	Independent Expert Advisory Group on SAGE Evaluation/WHO Department of Immunizations, Vaccines and Biologicals (IVB)
Link to the evaluation	https://www.who.int/immunization/policy/sage/sage_wg_evaluation_may2018/en/
Evaluation Plan	
Unit Responsible for providing the management response	UHL/IVB
<p>Overall Management Response: WHO and the SAGE Secretariat welcome and accept the recommendations of the evaluation (all but one sub-recommendation).</p> <p>The evaluation of SAGE 10 years after an initial review of SAGE and related normative functions in 2008, guided by an external advisory body (EAGSE), has provided management with invaluable recommendations to ensure SAGE continues to function as a high-level policy and strategy advising body. The main areas of advice cover the scope of SAGE in a changing and evolving environment for vaccination, measures to ensure relevance, reach and optimal impact of recommendations, and recommendations related to the effective functioning of the committee. The timing of the evaluation was optimal in relation to the development of a new 10 year immunization strategy (IA2030) and WHO's transformation agenda.</p> <p>The management is in process of taking on board most of the recommendations, and a number have already been fully implemented (e.g. the agenda setting process); others will take more time. A major conduit for the implementation of the recommendations is the revision of the terms of reference (ToR) and standard operating procedures (SOP) for both SAGE as well as its subgroups, the SAGE working groups. This work has in essence been completed and is under final review by the WHO Department on Quality, Norms and Standards (QNS). In parallel, IVB is updating and expanding its guide for the development of evidence-based recommendations that describes SAGE's on approaches for developing policy guidance, but also for advice on systems-related and strategic questions. Various measures to improve work effectiveness have been implemented, some triggered by the COVID pandemic and the need to optimally use electronic channels of communication, which have been applied to SAGE.</p> <p>An important consideration is the continuous assessment of impact and relevance of the advice provided by SAGE. For certain products resulting from SAGE advice, such as policy recommendations on vaccine use, the information is routinely monitored. For other recommendations, impact measures would need to be developed, such as approaches to better understand implementation challenges. The IVB Department will take this work forward.</p> <p>Lastly, adequate human and financial resourcing remains a considerable challenge and avenues need to be found to support core normative work in a stable and independent manner.</p>	
First Management Response Status: <i>In progress</i>	Updated Management Response Status: <i>in progress</i>
First Management Response Date: September 2020	Updated Management Response Date: <i>11 May 2021</i>
Overall update on the actions taken since September 2020	Due to the heavy involvement of the SAGE secretariat in the Covid-19 response, no actions could be taken in the past 6 months.

Recommendations and Action Plan

Recommendation 1 (*SAGE goals, mandate, mission and scope*)

A. WHO IVB to modify the SAGE ToR to more clearly reflect the primary goals and scope of SAGE as part of the broader WHO Programme of Work and the global post-2020 immunization strategy. This should include a focus on:

- immunization across the life course;
- impact at country level;
- achieving high and equitable vaccination coverage;
- integration into UHC and PHC

B. WHO IVB to modify SAGE's objectives for enhanced focus and clarity with specific reference to:

- Evidence-based recommendations on the use of vaccines and immunization to reduce the burden of vaccine-preventable disease over the human life course;
- The use of vaccines and immunization to respond to public health priorities, including the use of vaccines in the context of vaccine shortages and public health emergencies;
- Challenges to achieving and sustaining high and equitable vaccination coverage, including vaccine-preventable disease (VPD) surveillance, data quality and birth registration;
- Monitoring and evaluation of the adequacy of progress towards the achievement of the goals of VPD control worldwide in light of GVAP and the post-2020 strategy and establishment of an accountability framework;
- Engagement of WHO in partnerships that will enhance the achievement of global immunization goals;
- Integration of immunization into the broader context of Sustainable Development Goals, UHC and PHC.

Management response	Accepted Agreed that SAGE ToR needed update to reflect the priorities of the coming decade in immunization; stronger emphasis on systems issues, reference to the new 10-year strategy on immunization (Immunization Agenda 2030, adopted by WHA in 2020)				
Status	<i>In progress</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
SAGE ToRs modified reflecting alignment with WHO GPW13 and global post-2020 immunization strategy	IVB	Q4 2020	<i>In progress</i>	SAGE ToR as well as SAGE working group ToR have been completely revised and are currently under final review by WHO norms and standards team. Finalization anticipated by end of 2020. They emphasize the scope of SAGE in relation to guidelines, strategies, monitoring of progress and strategic advice.	ToR and SOPs are still under revision

				Standard operating procedures have been updated for effectiveness, simplicity and compliance with organizational rules. Exchange of information and coordination at secretariat level with relevant high-level advisory committees established (MCA STAGE, STAG-IH, MPAG malaria) Health systems and other relevant considerations considered in SAGE working group ToR	
SAGE Objectives and Scope of Work clarified	IVB	Q4 2020	<i>In progress</i>	Have been developed and cleared in IVB; under final review QNS	No update required

Recommendation 2 (SAGE in the next decade):

SAGE to ensure that emerging systemic issues in the context of the sustainable development goals such as urbanization, humanitarian emergencies, migration, ageing populations, climate change and a shift of focus from mortality to morbidity reduction are taken into account in its work of making evidence-based recommendations.

Management response	Accepted Action taken through the revision of SAGE ToR and Scope of work, as well in the work of subgroups as relevant				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Emerging systemic issues in the context of the sustainable development goals (e.g. urbanization, humanitarian emergencies, migration, ageing populations, climate change and a shift of focus from mortality to morbidity reduction) considered by SAGE when making recommendations.	IVB/APS and technical units	2020	<i>Implemented</i>	Items relevant to emerging systemic issues (such as urbanization, humanitarian emergencies, migration, ageing populations) are addressed at a technical level in the SAGE working groups. Their TORs have been updated. Secretariat increasing its explicit consideration of systems issues in vaccine policies	No update required.
Considered in the development of terms of reference for policy updates and their plans of work; and in the prioritization of agenda items;	IVB/APS and technical units	Continuous	<i>Implemented (in conjunction with new working groups)</i>	The recommendation made by the evaluation is in line with priorities highlighted in the new immunization agenda, and is reflected both in the priority setting process, and in the technical work to prepare policies; the SAGE working group on COVID-19 vaccination being a good example	No update required.

Recommendation 3 (Research and Development):

SAGE to establish mechanisms to ensure the identification of knowledge gaps requiring further upstream vaccine and operational research to enable SAGE to fulfil its functions. This is to be done in close alignment with other WHO immunization advisory groups (e.g., on product development, implementation research and immunization practices), and with relevant immunization partners.

Management response	Accepted Under the areas of advice for SAGE, the following area has been added: "Strategic foresight and innovation – This consists of identifying research needs and areas that require innovation in order to achieve VPD control targets more effectively." In addition, A SAGE representative to attend both product research and implementation research specialized advisory groups and report back to SAGE as needed (this measure was already in place)				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Mechanisms established, in close alignment with other WHO immunization advisory groups, to ensure identification of knowledge gaps requiring further upstream vaccine and operational research	IVB/APS and IVB/IVR	Continuous	<i>Implemented</i>	SAGE Working Groups systematically identify knowledge gaps from their review of evidence, including an assessment of needs for future products/ products in the pipeline. High level research needs outlined systematically in vaccine position papers. One SAGE member serves as liaison to related technical advisory bodies on product development and implementation research.	No update required.

Recommendation 4 (SAGE and other WHO immunization advisory committees):

WHO IVB to ensure complementary mandates, functions, roles and responsibilities of all WHO HQ immunization advisory groups as well as their contribution to the SAGE process of evidence review for recommendations. In particular:

- SAGE to proactively seek technical inputs from the relevant WHO immunization advisory groups through the IVB Director or the SAGE Secretariat.
- SAGE to ensure that the relevant reports of the immunization advisory groups to SAGE be integrated into the corresponding SAGE sessions and linked to SAGE recommendations.

Management response	Accepted Work processes have been improved, Management is reviewing scope and mandates of related technical advisory bodies to ensure complementarity				
Status	<i>In progress</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Increase complementarity of mandates, functioning, roles and responsibilities of different WHO HQ immunization advisory committees with SAGE	Director IVB	By Q1 2021	<i>In progress</i>	Terms of reference and scope of other technical advisory bodies on immunization, reporting to the Director of IVB are being reviewed and streamlined.	ToR and SOPs are still under revision

				<p>One committee has been closed (immunization practices). Work processes have been aligned through departmental planning processes.</p> <p>Clarification has been provided on which needed evidence elements for SAGE deliberations require review by a technical advisory body.</p>	
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<p>Recommendation 5 (<i>Principles of working with regions and countries</i>):</p> <p>WHO IVB in collaboration with Regional Offices to strengthen existing channels or develop new ones to ensure appropriate consideration of all regional and country needs in defining the SAGE agenda and in formulating SAGE guidance, including those for low, middle and high-income countries.</p>					
Management response	<p>Accepted</p> <p>Management agreed to a more pro-active engagement with regions for agenda setting, and on monitoring implementation challenges</p>				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Strengthened process for considering regional and country needs in defining SAGE agenda/formulating SAGE guidance, including for LMICs.	IVB	Q1 2020	<i>Implemented</i>	<p>A more formal consultative process for SAGE agenda setting involving regional offices has been developed and implemented.</p> <p>Regular department-level consultations with regional offices being implemented, including considerations for normative guidance.</p> <p>Practical measures being taken to improve day to day interaction with regional offices.</p> <p>Regional offices systematically asked for input on the definition of scope of work of new SAGE working group, with the invitation to participate</p> <p>(Actions also related to Recommendation 6)</p>	No update required.

Recommendation 6 (SAGE-RITAG-NITAG policy-making chain):

- A. WHO IVB in collaboration with Regional Offices to define a framework describing roles, responsibilities and linkages between SAGE, RITAGs and NITAGs.
- B. WHO IVB to work with Regional Offices to set up an institutional mechanism or platform for regular interaction with RITAGs and NITAGs to allow for country and region specific questions to be proposed for SAGE advice and for provision of feedback on the implementability of SAGE recommendations.
- C. WHO IVB to encourage Regional Offices and RITAGs to include a standing agenda item for discussion of SAGE recommendations in RITAG and inter-country EPI managers meetings.

Management response	Accepted. Management is taking forward this recommendation in conjunction with an intensified and more regular communication with regional offices. Management is also coordinating activities in support of country level decision-making, including the policy-related tasks.				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
IVB work with Regional Offices to set up an institutional mechanism or platform for regular interaction with RITAGs and NITAGs to allow for country and region-specific questions to be proposed for SAGE advice and for provision of feedback on the implementability of SAGE recommendations.	IVB /Regional Offices, RITAGs	Q1 2020	<i>Implemented</i>	In addition to the points mentioned under Recommendation 5, the following steps are being taken to enhance the relevance of SAGE's work for regional decision-making through RITAGs and national decision-making through NITAGs. - HQ setting up a process to systematically collect RITAG recommendations to HQ and to coordinate follow-up (under development) Regional offices systematically invited to participate in SAGE preparatory teleconferences Interaction with NITAGs: while interaction with NITAGs are the primarily the role of regional offices, NITAGs are systematically invited to attend SAGE meetings (and side events are being organized). Support of NITAGs coordinated between global and regional level: HQ global coordination processes for NITAGs have been connected to SAGE by inviting the chair of Global NITAG Network to SAGE meetings, and by pro-actively disseminating relevant SAGE documents through a NITAG online platform (NITAG resources Centre NRC). During onsite SAGE meetings, Global NITAG Network side meetings are organised to obtain feedback from countries and allow interaction between SAGE members and NITAGs.	No update required.
Regional Offices and RITAGs to include a standing agenda item for discussion of SAGE recommendations in RITAG and inter-country EPI managers meetings.	IVB Regional Offices/RITAGs	Q1 2020	<i>Implemented</i>	SAGE agenda setting includes a consultation process with regional offices; most RITAG meetings have a scheduled slot for interaction with HQ on normative matters	No update required.

Recommendation 7 (<i>Relations with global stakeholders</i>): A. WHO IVB to define rules of engagement of SAGE with stakeholders and individual subject matter experts, including the ‘key technical partners’ and WHO focal points, to ensure the provision of highest quality input while avoiding undue influence. B. SAGE to engage in regular dialogue with relevant global immunization stakeholders to have a current understanding of their priorities, plans, and challenges. Such dialogue should ensure timeliness and relevance of SAGE recommendations, as well as optimizing the ability of recommendations to shape stakeholder planning and commitment of resources, and to be implemented.					
Management response	Accepted The revised SOP’s for SAGE and its subgroups (“SAGE working groups”) make specific reference to the role of partners, private sector etc, in accordance with Organization-wide rules (e.g. FENSA); regular discussions with key technical partners (Gavi, UNICEF, CDC) on policy needs have been put in place				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Develop SAGE SOPS for engaging stakeholders, experts and technical partners for obtaining input and avoiding undue influence.	<i>IVB CRE</i>	<i>Q4 2020</i>	<i>Implemented</i>	Standard operating procedures of SAGE have been revised with due consideration of organizational rules. <i>SOPS under final review.</i>	No update required.
SAGE regular dialogue with global immunization stakeholders, and tracking of SAGE recommendation uptake/implementation.	<i>IVB</i>	<i>Q1 2020</i>	<i>Implemented</i>	Secretariat of SAGE engages in regular consultations within WHO (e.g. Medicines department) and key technical partners (e.g. Gavi) on policy needs and policy implementation challenges.	No update required.

Recommendation 8 (<i>SAGE membership and chair selection</i>): A. SAGE to ensure access to all relevant expertise in its decision-making process in light of the enlarged scope of the immunization agenda, specifically covering the fields of ethics, health economics, social sciences, communication sciences and maternal health. B. WHO IVB to establish ToR for the SAGE chair and vice-chair to address the issue of high work load and the need to delegate some of the chair’s tasks.					
Management response	Accepted Reflected in the updated SAGE ToR and SOP’s and gradually being implemented as SAGE membership rotates.				
Status	<i>In progress</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Review/adapt SAGE membership in reference to different expertise/skill mix	<i>IVB</i>	<i>Q4 2020</i>	<i>In progress</i>	Expertise mix has been defined in the updated SAGE ToR &SOP; and is being	ToR and SOPs are still under revision

(e.g. ethics, health economics, social sciences, communication sciences, maternal health)				considered when new members are being selected to join SAGE	
SAGE ToRs for Chair, Vice Chair reflecting workload balance and respective roles and responsibilities	IVB	Q4 2020	In progress	ToR/attributes for SAGE Chair and Vice Chair have been developed, and are in internal clearance.	ToR and SOPs are still under revision

Recommendation 9 (SAGE Agenda Setting):

- A. WHO IVB to ensure systematic interaction with Regional Offices and RITAGs for identification of topics for the SAGE agenda in close consultation with NITAGs and country offices.
- B. WHO IVB to consider establishing a Steering Committee for the collection, triaging and prioritization of agenda topics.
- C. SAGE to focus its agenda on ‘for decision’ and ‘for discussion’ items and to reduce the time spent on ‘for information’ sessions.

Management response	Partially accepted (A and C). The SAGE Secretariat has enhanced its processes for collecting, triaging and prioritizing agenda topic. All final decisions on the agenda and workplan rest with Director IVB. For that reason, management did not follow up on the recommendation (B), and relies on an enhanced consultative process for agenda setting as described below. Emphasis in plenary meetings is on recommendations and not information.				
Status	Implemented				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Agenda setting process enhanced (with interactions with Regional Offices, RITGS, NITAGS, Country Offices)	IVB(RO)	Q1 2020	Implemented	Transparent and inclusive SAGE agenda setting process has been established and web-posted; entails a consultative step with regional offices, and input from key stakeholders. SAGE now keep a list of items that constitutes its plan of work that is posted on the web (“shortlist”).	No update required.
Clarify nature of agenda decision points	IVB/APS	Q1 2020	Implemented	SAGE agenda emphasises decision/recommendation items over information items.	No update required.

Recommendation 10 (<i>Decision-making and Working Group processes</i>):					
A. SAGE to communicate more clearly the decision-making criteria used for the development of SAGE recommendations and to more clearly link GRADE and Evidence to Recommendation tables to specific sessions and resulting reports.					
B. WHO IVB to shorten the lead times for establishment of WGs and to update their SOPs to allow for comparable functionality.					
C. WHO IVB to assure that the establishment and functioning of SAGE WGs is done independently of donor and funder support.					
D. SAGE to establish a process for the timely revision of and update to its position papers in case of minor policy changes.					
Management response	Accepted. However, management agrees with the recommendations but notes that implementation may be constrained by resources limitations and conflicting priorities.				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
SAGE decision-making criteria communicated and based on evidence.	IVB	Q1 2020	<i>Implemented</i>	The SOPs of SAGE working groups have been updated to emphasize the evidence-based decision-making process. All relevant documents are web-posted. SAGE guidance for evidence-based decision-making is being updated.	No update required.
SAGE WGs independent functioning ensured, including updating their SOPs to allow for comparable functionality	IVB	Q1 2020	<i>Implemented</i>	Secretariat ensures comparable functionality of working groups; SAGE interim recommendations, or SAGE emergency meetings outside the scheduled bi-annual meetings increase flexibility and responsiveness of working. (Interim recommendations have been issued for yellow fever, Ebola, influenza, and are under preparation for COVID)	No update required.
SAGE process for timely revisions and updates to position papers (minor policy changes)	IVB	Q1 2020	<i>Implemented</i>	SOPs allow for simplified processes for minor policy updates.	No update required.

Recommendation 11 (<i>SAGE meeting setup and modus operandi</i>):					
A. The SAGE Secretariat to ensure appropriate preparation of meetings, curation of topics and presentations, e.g., by use of standard templates, and strengthened time management.					
B. The SAGE Secretariat to establish longer closed briefing sessions for SAGE members allowing for in-depth review of more complex issues prior to the open SAGE meetings.					
C. The SAGE chair to proactively encourage participation of all SAGE members in plenary discussions.					
D. The SAGE Secretariat to establish a procedure to assess the meeting agenda and process, including the quality of presentations, materials and discussions immediately after a meeting, e.g., through a representative survey of registered meeting participants.					
E. The SAGE Secretariat to explore and pilot utilization of state-of-the-art communication and IT technologies for SAGE and its Working Groups to improve efficiencies, allow for better and more frequent interaction and potentially reduce the need for travel.					

F. WHO IVB to explore holding a third SAGE meeting per year via web-conference to allow discussion of matters of importance and to decompress the SAGE face-to-face meeting agenda.					
Management response	Accepted Management overall agrees with recommendations and implements them in a process of continuous quality improvement, regularly surveying SAGE members and other meeting participants; management has also introduced technology changes which have been precipitated through the COVID pandemic.				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Enhanced process for meeting preparation, curation of topics and presentations, e.g., by use of standard templates, and strengthened time management.	IVB/APS	Q1 2020	<i>Implemented</i>	SAGE Secretariat developing specific process improvements, including attention to time and information flows, questions to guide SAGE members' deliberation, and use of standard templates to summarize session objectives and expected outcomes.	No update required.
SAGE deliberative process enhanced, including virtual methods (ref: recs, 11B and 11E)	IVB	Q1 2020	<i>Implemented</i>	Precipitated by COVID, SAGE has been using virtual TC gatherings for management meetings, technical briefing but also plenary meetings. We remain committed to decision-making in plenary meetings, though. Electronic workspaces have become the norm, and all meeting materials are circulated electronically.	No update required.
SAGE Chair proactively encourages participation of all SAGE members in plenary discussions.	IVB	Q1 2020	<i>Implemented</i>	Short guidance for Chair on moderation of meeting discussions prior to a decision session being developed and discussed.	No update required.
Learning and assessment of meeting agenda and process, quality of presentations, materials and discussions immediately after a meeting	IVB	Q1 2020	<i>implemented</i>	Brief survey to selected registered meeting participants for meeting evaluation is implemented after plenary SAGE meetings.	No update required.
Possible third SAGE meeting per year via web-conference	IVB	Q2 2020	<i>implemented</i>	Virtual meetings have been held to develop interim recommendations, and others are in planning. A third scheduled virtual meeting of SAGE has not yet been decided.	No update required.

Recommendation 12 (<i>Conflict of interest management</i>): WHO IVB to refine the scope of what constitutes a Col according to WHO-wide Col policies, including interests beyond industry relationships, e.g., academic, intellectual, regional, and national interests, and upgrade the process for Col management.					
Management response	Accepted Management is proceeding in consultation with CRE; more specific guidance on conflict of interest typical for clinical researchers has been developed and approved by CRE.				
Status	<i>Implemented</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Update and apply WHO Col policies and procedures to SAGE context and needs	IVB CRE LEG	Q1 2020	<i>Implemented</i>	In collaboration with CRE, IVB has developed more specific guidance on the definition of conflict of interest in the field of vaccines and immunization, and developed criteria on the management of conflict of interest.	No update required.

Recommendation 13 (<i>Communication and dissemination of SAGE output</i>): A. WHO IVB to explore additional communication channels in collaboration with Regional Offices and RITAGs, i.e., in addition to ‘Weekly Epidemiological Records’ and ‘Vaccine’ publications, for dissemination of SAGE outputs. B. WHO IVB to broaden its engagement and communication with multiple stakeholders including e.g., national immunization programme directors, professional associations and other immunization partners, and ensure the appropriate tailoring of communication messages and tools according to target audiences.					
Management response	Accepted Management agrees in principle with more pro-active communication on SAGE’s work and deliberations in accordance with WHO’s rules and procedures. IVB’s engagement with stakeholders will mostly remain at global level or through regional offices. Tailored communication to national bodies is beyond IVB’s resources.				
Status	<i>In progress</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Increase dissemination of SAGE outputs/products, including identification of new communication channels	IVB	Q2 2021	<i>In progress</i>	Work in progress in conjunction with WHO corporate revision of its website. Meanwhile, meeting reports and policy is being published in the “Weekly Epidemiological Record”, and all relevant background materials are web-posted.	SAGE uses dedicated web pages and NITAG resource center to disseminate information
Plan to broaden targeted communication and engagement with multiple stakeholders	IVB	Q2 2021	<i>In progress</i>	Initial efforts include a) survey key stakeholders b) explore creation of new email lists to reach other audiences (e.g. professional associations) and c) dispatch information via the Global Nitag Network, Technet, Global Immunization Newsletter.	

Recommendation 14 (<i>Secretariat role and resources</i>):					
A. WHO IVB to perform an assessment of the resources required to implement the recommendations proposed by the EAGSE and to ensure a sufficiently staffed SAGE secretariat to facilitate the necessary processes.					
B. WHO IVB to ensure that SAGE, SAGE Working Groups and SAGE Secretariat resources come from WHO core funding.					
Management response	Accepted Management has conducted a comprehensive review of the departmental priorities and structure, in conjunction with Organization-wide reform. Resources requirements have been assessed, and funding opportunities explored.				
Status	<i>In progress</i>				
Key actions	Responsible	Timeline	Status	Comments	Update since Sept 2020
Resources (financial and staff) needs assessed for SAGE Secretariat to implement recommendations	IVB	Q2 2020	<i>implemented</i>	Funding needs have been assessed in conjunction a comprehensive departmental review.	No update required.
Financial resources for SAGE identified	IVB ADGO/UHL CRM	Q2 2021	<i>In progress</i>	Securing core funds for normative work represent a significant hurdle and more work is needed. If disease specific funding is used for working groups, particular attention is given that independence from any external agendas is assured.	Funding situation unchanged