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# Report of the Strategic Advisory Group of Experts (SAGE)

Geneva, 1-3 November 1999



**DEPARTMENT OF VACCINES  
AND BIOLOGICALS**



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# Executive summary

In the 1980s the Global Advisory Group advised the Expanded Programme on Immunization (EPI), and during the 1990s the Scientific Advisory Group of Experts advised the Global Programme for Vaccines and Immunization. Because a number of highly technical committees now advise WHO's Department of Vaccines and Biologicals (V&B) on specific issues such as polio eradication and immunization safety, a need was perceived for a committee that could take a broad view of WHO's vaccine-related work. The Strategic Advisory Group of Experts (SAGE) was therefore established.

In order to plan for future needs, V&B developed a strategic plan for the next biennium, covering the following areas of work: **innovation, immunization systems and accelerated disease control**. For each a priority project was selected, namely **accelerated vaccine introduction, immunization safety and polio eradication**.

The first meeting of SAGE, whose members were selected for their expertise and geographical representation, was convened on 1-3 November 1999 in Geneva to advise V&B on the three main strategic aspects of its programme.

## A. Innovation

### *Accelerated vaccine introduction*

Some new vaccines against major causes of morbidity and mortality are available currently, and some will become available in the next 10 years. As they become available, they are being adopted rapidly by industrialized countries, but the uptake of these new vaccines in developing countries has been much more restricted. Limiting factors have been a delay in demonstrating efficacy in developing country settings, lack of information on disease burden and cost effectiveness, problems with supply and financing, and lack of technical expertise for their introduction. In order to meet this challenge, V&B has established the Accelerated Vaccine Introduction (AVI) priority project. SAGE supported the strategies and major work elements of AVI and suggested areas that required additional emphasis. Sustained improvement in immunization systems demands increased commitment to immunization in general and the introduction of new vaccines. As part of the project, and in collaboration with other partners, WHO should foster ownership of the introduction of new vaccine programmes in the developing world. This should include advocacy at the international level and support for the production of advocacy and IEC materials at the national and local government levels for both health workers and the public.

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SAGE noted the success of PAHO's revolving fund as a means of facilitating the introduction of Hib and other new vaccines. This model should be considered for use by other Regions and country groupings.

When the introduction of new vaccines into developing countries is being considered, not only the reduced disease burden and cost-effectiveness of vaccines should be taken into account but also the comparative impact on overall cost of investment in prevention and treatment.

WHO should communicate effectively and frequently with industry on vaccine priorities, epidemiological findings, and vaccine formulation preferences.

Additional work is needed to clarify how WHO can facilitate the development and use of vaccines of Regional importance, such as group A meningococcal, dengue, yellow fever, rabies, tick-borne encephalitis and Japanese encephalitis vaccines.

SAGE noted the good progress made by the various Scientific Working Groups that had responsibility for developing a specific vaccine or vaccines, bringing the together the world's experts in these fields.

### *Innovation in research*

Essential to successful immunization programmes is a strong research programme leading to the introduction of new vaccines, new presentations and new technologies. SAGE commended V&B's excellent programme of research and development, which has underlined how modest investment can produce major progress. SAGE urged that this role should continue. A number of initiatives were endorsed, including:

- a) **Intercluster Vaccine Research Initiative:** There was support for this Initiative and its opportunities to advocate selected efforts in research and development. SAGE commended WHO's continuing efforts to consolidate the different vaccine research components in a single, more interactive and efficient Organization-wide activity. Of particular interest was the link with research into vaccines against malaria and HIV/AIDS.
- b) **Pneumonia:** SAGE endorsed the expanded pneumonia research programme proposed by the Secretariat.
- c) **Tuberculosis control:** SAGE endorsed V&B's general strategic plan for the development of an improved tuberculosis vaccine and welcomed the efforts undertaken by V&B to maintain a constant dialogue with all the stakeholders in this field.
- d) **New approaches to the stabilization of vaccines:** SAGE commended WHO's initiative on the development of drying processes aimed at achieving long shelf life and thermostability of vaccines. Sugar-drying provides one example of the work done in this field. Given the potential impact of thermostable vaccines on delivery systems, especially in developing countries, the cost-benefit, safety and efficacy of these vaccines should be thoroughly assessed and a report of progress should be presented to the next SAGE meeting. SAGE acknowledged that close collaboration with industry was essential if this wide-reaching change in vaccine development and manufacturing was to be fruitful.

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## B. Immunization systems

### *Immunization safety*

While immunization can be enormously beneficial, it can also be harmful if vaccines are not of high quality or are not administered safely. SAGE complimented V&B for its proactive approach and comprehensive set of activities aimed at ensuring vaccine safety. It acknowledged the importance of advocating safety and of building capacity at national level. It supported the implementation of a series of training activities, the development of a standard set of information documents, and the fostering of collaboration between various interested parties at the national and sub-national levels. It was felt desirable to identify regional expertise capable of responding to safety issues.

Two committees have been set up to guide the work of V&B in this area – the Steering Committee on Immunization Safety (providing overall guidance to V&B on managing the Immunization Safety Priority Project) and the Vaccine Safety Advisory Committee (providing impartial, high-quality scientific advice to WHO on specific issues relating to vaccine safety as they arise). While the formation of these committees was endorsed, the need was expressed to harmonize their work with that of SAGE. They should both report to SAGE at least once a year. SAGE fully endorsed all the main recommendations from the recent inaugural meeting of the Steering Committee of the Immunization Safety Priority Project<sup>1</sup>.

SAGE commended WHO's initiative in establishing a global advisory committee on vaccine safety as a proactive and co-ordinated mechanism for reliable and independent scientific assessment of vaccine safety issues. SAGE noted that the Advisory Committee must be acknowledged for its independence, scientific integrity, excellence and efficiency, including its rapidity of response. It must not be compromised by interference in its decisions by others for reasons of political or other expediency. The Committee will report to the Director of V&B, who must decide when to report to SAGE and must ensure that strategic decisions affecting immunization programmes are appropriately addressed. Decisions regarding vaccine safety issues dealt with by the Committee will be reviewed periodically when and if additional important data become available. SAGE noted with approval that the Committee included all interested parties, including industry, in its review of scientific evidence. SAGE strongly encouraged support for regulatory research and stressed the importance of communication and collaboration between the laboratories and the Immunization Safety Priority Project.

SAGE noted the important activities undertaken to improve the safety of injection devices, especially in the field of AD syringes. The Committee endorsed the transition to AD syringes for all immunization activities by 2003, and supported WHO's role in developing a joint WHO/UNICEF statement on the safety of all injections related to immunization. SAGE urged the Director to consider whether a similar statement should be developed to cover all injections, whether or not they were given in the immunization setting.

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<sup>1</sup> A full report is available from the Vaccine Assessment and Monitoring Team of the Department of Vaccines and Biologicals, WHO Geneva.

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WHO should provide guidance to National Regulatory Authorities (NRAs) on matters relating to injection technology. SAGE recommended that a working group be asked to develop guidelines that would assist NRAs in regulating injection equipment, and to further analyze the role that WHO might play in monitoring the quality of injection equipment supplied through UN purchasing agencies. A report on the outcome of this analysis should be presented to SAGE in 2000.

### *Improving access to immunization*

Access to immunization services and high coverage for the scheduled routine doses of vaccine are fundamental requirements. Around 80% of the world's children have been reached but the other 20% are hard to reach, and creative ways of providing access to them are needed.

SAGE noted that immunization coverage was very low in several regions, especially in some sub-Saharan countries. The committee recognized the importance of developing strong health systems as a means of providing immunization services to those most in need, particularly the impoverished. It recommended that WHO should give special attention to strengthening the ability of health systems to deliver priority programmes.

SAGE noted that the strategy of providing sustained outreach services (SOS), aimed at reaching the unreached, was heavily resource-dependent but did attempt to improve equity of access to essential health services and immunization in poor countries. SAGE endorsed the introduction of SOS in a number of African countries as one of several interventions needed to strengthen immunization systems.

SAGE supported the concept of linking successful components of immunization programmes and making the availability of external funding contingent on demonstrating the capacity to use it efficiently, safely and in a sustainable way. SAGE commended the proposal to link financial inputs to successful performance as revealed by indicators. The matching of finance to performance at district level has proved successful in several national immunization programmes.

SAGE recognized that an improvement in management skills was essential for progress. The management of immunization programmes must take into account their changing environment, while maintaining essential functions. Assessment and

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