Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE recommended that WHO gives a clear signal on the priority for wider use of pneumococcal vaccine in children.

Lack of clarity of demand is a critical factor inhibiting industrial scaling up of manufacturing capacity. This uncertainty needs to be overcome since validated demand forecasts are essential for the commitments required from industry that will make this vaccine available at affordable prices.

In particular, evidence was required through studies on disease burden of the cost benefit of using pneumococcal conjugate vaccines and the feasibility of vaccine delivery to all vulnerable groups.

Pneumococcal serotype prevalence studies, undertaken in different settings, are required to judge the appropriateness of the conjugate vaccine to be used. A firm position from SAGE will be required once serotype prevalence studies are completed to judge the appropriateness of the conjugate vaccine available.

(SAGE) recognized that a global recommendation, made before resolution of funding and supply issues, could leave vulnerabilities that have been experienced with the implementation of Hib vaccine.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

(SAGE recognized) that immunization schedules in use today vary greatly around the world, and it is unlikely that a single, uniform immunization schedule would suit all countries. WHO should aim to provide countries with advice on the parameters to be considered when they select a schedule. There was unanimous support for a new review of the evidence base, and agreement that changes in schedule are not appropriate without strong evidence to demonstrate benefit.

SAGE recommended that a review of the issues surrounding the primary schedule, boosters and adolescent vaccination should be undertaken. This should incorporate disease control strategies, immunology, operational aspects of health services (not just vaccination services) and economics.
Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE recommended that WHO should provide support to developing countries for the development of national, seasonal and pandemic influenza vaccination policies. All countries should develop pandemic preparedness plans that include strategies for the deployment of vaccines when these become available. SAGE stressed that countries must not depend solely on vaccines for pandemic control because lack of vaccine or at best shortage will be a reality in most countries. With the goal of facilitating equitable and timely access, WHO should continue to play a role in advising on priority groups for immunization with pandemic vaccine (http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2004_8/en/index.html).

WHO should provide advice for enhanced surveillance for early detection of new influenza strains and of the onset of a pandemic, if it occurs. WHO should pursue its efforts in strengthening the capability in developing countries of health ministries and national regulatory authorities to facilitate the movement of samples and to ensure prompt registration of pandemic vaccines. Global regulatory convergence should be considered, and WHO should facilitate progress in this direction.

WHO should support research and development for pandemic and seasonal vaccines, including alternative and more effective methods of vaccine delivery such as intradermal and intranasal vaccination, improved vaccines and novel production technologies. SAGE noted that there is currently no influenza vaccine production capacity in the African region. Where appropriate, WHO should facilitate developing countries in establishing local capacity for production of influenza vaccine (including pandemic vaccine) based on manufacturers of vaccines of assured quality and should provide support for relevant technology transfer.

WHO should collaborate with expert groups to model the impact of different vaccination strategies in pandemic control, including the possibility of strategic deployment of vaccines, under various epidemiological settings. The risks and benefits of diverting some current vaccine production facilities to the production of influenza vaccines should be investigated. This should be taken forward urgently by WHO as it may provide a means of expanding vaccine production capacity more effectively than reliance on increasing use of seasonal influenza vaccination. The possible negative impacts on supplies of other vaccines should be considered.

WHO should ensure that the expertise in rapid mobilization for mass immunization is included in influenza preparedness planning. In addition, similar considerations should be given to access and distribution of antiviral medication.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE suggested that the GIVS research agenda be expanded beyond clinical trials to include other areas of research, such as health systems research, acceptability and community preparedness studies, epidemiological studies and cost-effectiveness studies.

SAGE praised the overall GIVS costing model and encouraged its further refinement and completion by WHO. Specifically, it was noted that the costing of surveillance and monitoring and for advocacy and communication may have been underestimated.
Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE requested that the WHO position paper on mumps vaccines be revised, drawing on the conclusions and recommendations from the recent consultation on use of mumps vaccine in the Eastern Mediterranean Region. The revision should take into consideration the accumulating global experience that high coverage with 2 doses of measles-mumps-rubella vaccine (MMR) is required to effectively prevent mumps outbreaks.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

Additional information on the safety of different mumps vaccine strains is available from country experiences with use of mumps vaccine in mass campaigns and routine settings. These data should be reviewed by the GACVS and the resulting conclusions included in the revision of the WHO mumps position paper.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

The WHO secretariat should make special efforts to collaborate with industry to increase global availability of MMR vaccines that contain strains of mumps vaccines with the best safety profile.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE requested the updating of the WHO position paper on JE immunization.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE supported the efforts of WHO to scale up activities relating to influenza pandemic vaccine development, evaluation and capacity building, and the monitoring of seasonal influenza vaccine supply and uptake.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE recognized the critical role that WHO should play in the international coordination of research and evaluation of influenza pandemic vaccines.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE considered that the GIVS goal of 90% (measles) mortality reduction by 2010 remained appropriate. SAGE recommended that work be undertaken to prepare for discussions on the feasibility of a global elimination goal.
WHO should ensure that there is unrestricted sharing of samples and vaccine strains internationally.

One non-traditional approach to immunization financing is Advanced Market Commitments (AMCs.) The essence of the AMC mechanism is an agreement made by donors to guarantee a pre-set fixed price for a fixed market size (number of doses) that will be paid for a vaccine that meets a specific pre-established "target product profile"; this guarantee is made with the understanding that the recipient (developing) countries agree to make co-payments to purchase the vaccine.

Once the commitment is exhausted, manufacturers, having benefited from the subsidy, are contractually obliged either to continue to sell to developing countries at a price that the countries can accommodate over the long term or to license their technology to other manufacturers.

Three major roles were identified for WHO: (i) to provide recommendations on target product profiles through SAGE; (ii) to conduct the prequalification process for AMC-eligible products to be purchased through United Nations agencies; and (iii) to provide technical advice on evidence-based decision-making, priority setting, the introduction of new vaccines, and health-system financing to governments of AMC-eligible countries. SAGE recommends that WHO assumes these functions.

During discussion, it was recommended that the target product profile include elements aimed at reducing systems costs (especially related to the cold chain), such as specifying the presentation and vial size.

SAGE endorsed the role that is proposed for it - that is, to review WHO's proposals for the target product profile and to make a recommendation on the most appropriate profile.

SAGE recommends that the GAVI Alliances secretariat, the World Bank and the AMC independent advisory committee further refine and clarify the AMCs operating mechanisms so that potential obstacles to effective implementation are addressed.

SAGE recommends that more in-depth investigation should be done of the investments in immunization systems required to support the introduction of pneumococcal vaccine in AMC-eligible countries (which are also GAVI-eligible countries). SAGE also recommends that the impact of different copayment scenarios on the immunization financing profiles of AMC-eligible countries should be further modelled and investigated using more accurate estimates of future demands from countries.
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The global framework (on immunization monitoring and surveillance) describes 2 strategic areas: surveillance for vaccine-preventable diseases and immunization monitoring. The ancillary function of funding surveillance and monitoring is added as a third section.

The vision of the global framework is that, by 2010, there should be an integrated epidemiological, laboratory and programme-monitoring network for the surveillance of vaccine-preventable diseases and monitoring of the performance of immunization programmes. This network will provide high quality information to measure the impact of vaccination and maximize the safe, effective and equitable use of vaccines at country, regional and global levels to reduce or eliminate the burden of vaccine-preventable diseases.

SAGE endorse the global framework documents with some modifications. Modifications suggested included: expanding the linkages to the IHR (International Health Regulations) by providing examples of how some vaccine-preventable diseases fit into the new IHR because they constitute a public health emergency of international health concern; including operational guidance on ways to implement this strategy at the local level in the Way forward section; defining key epidemiological data used in the furtherance of mathematical modelling; and emphasizing recent developments on surveys to monitor programmes and to validate estimates (for example, it is now recommended that Multiple Indicator Cluster Surveys take place every 3 years instead of every 5 years).

SAGE suggests that WHO should produce a clear dissemination plan for the global framework.
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE requested an urgent expert consultation to review all data on the immunogenicity of fractional doses (of meningococcal vaccine.)

SAGE recognizes the imminent threat of epidemic meningitis in the African Region and the serious shortage of vaccine should this scenario unfold. SAGE concluded that in the event of an epidemic and in the context of vaccine shortage, the national authorities of affected countries should undertake a risk-benefit analysis that recognizes the public health benefits of using fractional doses of licensed polyvalent polysaccharide vaccines during mass vaccination campaigns in order to provide protection to a larger proportion of the population. Limiting vaccination to narrower age groups at highest risk (that is, up to the age of 15 years instead of up to age 29) should also be considered.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE recognized the importance of activities targeting capacity building and the development of clinical trial sites to ensure that all phases of clinical trials could be conducted in a way that meets the highest scientific, legal, ethical and regulatory standards as well as ensuring that communities are involved in the process. It will be important to develop such sites in developing countries where future vaccines would offer the most benefit.

Recognizing the complex scientific questions that need to be addressed with novel vaccine technologies, SAGE encourages efforts to facilitate close interaction and early discussions between researchers and national regulatory authorities. Additional training of members of national regulatory authorities in scientific aspects should also be included in the training programmes that are being implemented by WHO and other international sponsors.

SAGE expressed its support for the work of WHO in the area of developing vaccines against HIV, TB and malaria in close cooperation with other international and national partners and confirmed the critical role WHO has in developing relevant policies, norms and standards to facilitate the highest scientific, regulatory and ethical standards of clinical trials worldwide.
Vaccination with licensed H5N1 vaccine is strongly recommended for laboratory workers involved in the following activities: large-scale production or manipulation of HPAI H5N1 viruses, working with these viruses over a long period, working with HPAI H5N1 viruses that are resistant to licensed antiviral compounds, or working with viruses with the potential for increased transmissibility in mammalian species.

For laboratory personnel working with H5N1 viruses but not involved in the activities described above, the risks and benefits associated with H5N1 vaccination should be evaluated before it is made available, and affected staff should be involved in decision-making regarding whether to be vaccinated.

Depending on the local risk of exposure and the nature of possible clinical exposure, vaccination is recommended for workers involved in the front-line response to possible H5N1 outbreaks in animals or humans.

The risk for people who may potentially come into contact with infected animals (for example, poultry farmers) cannot be quantified based on available information, although the risk has been evaluated as being lower than that for laboratory workers and first responders. H5N1 vaccination cannot, therefore, be recommended at present, but vaccine may be made available to people who have contact with poultry and who are in areas where there is a confirmed active outbreak, depending on the level of enzooticity, risk of exposure and effectiveness of other prevention measures in place. Currently, this does not involve large population groups, and careful risk assessment should be undertaken before vaccine is made available.

To date, there are no data indicating that the risk of infection from avian H5N1 influenza viruses for essential workers (that is, key workers in critical infrastructure sectors) outside of health-care workers, is higher than for other members of the population. Therefore, the evidence is insufficient to propose that H5N1 influenza vaccine should be made available to general essential workers during the interpandemic period in areas where HPAI virus is enzootic. In contrast, vaccination is recommended for health-care workers who evaluate and manage patients with suspected or confirmed H5N1 infection in designated outpatient or inpatient referral facilities. These health-care workers may be at a higher risk of infection than other health-care workers, especially if a virus with increased potential for human-to-human transmission emerges. Based on risk assessments made in specific geographical areas, licensed H5N1 vaccines may also be made available to other health-care workers in countries where avian H5N1 viruses are enzootic and where human cases continue to emerge and pose a threat of exposure to health-care workers. This includes health-care workers at a large number of primary health-care facilities where patients with suspected H5N1 infection may first present for treatment.

In countries affected by HPAI H5N1 influenza, the risk of infection in the general population remains very low. Since one cannot exclude a risk, albeit low, of vaccine-related serious adverse events, and at the present low level of risk of infection, H5N1 vaccination is not recommended to immunize the general population against infection with HPAI H5N1 virus.
Weekly Epidimiological Record, No. 15, 10 April 2009

There is insufficient scientific evidence to recommend the use of licensed human H5N1 influenza vaccines, or to propose that such vaccines be made available, in the interpandemic period for essential personnel or for the general global population, either to prime them or immunize them against infection with a potential pandemic H5N1 virus.

Weekly Epidimiological Record, No. 49, 4 December 2009

SAGE recommended the use of a single-dose of vaccine in adults and in adolescents aged >10 years, provided this use is consistent with the indications of national regulatory authorities.

Weekly Epidimiological Record, No. 49, 4 December 2009

The committee stressed that studies should be undertaken to assess effective dosage regimens in immunodeficient persons for whom 2 doses may be needed. Unless regulatory authorities have advised that a single dose of vaccine is adequate, SAGE recommends that where children have been prioritized for vaccination, then those aged >6 months and <10 years should receive 2 doses of vaccine. In the interests of public health, vaccine supplies should be used to give first doses to as many children as possible, with second doses following as further supplies become available, and subject to regulatory considerations.

Weekly Epidimiological Record, No. 49, 4 December 2009

When seasonal and pandemic vaccines are both inactivated, or when one is inactivated and the other is live attenuated, SAGE recommends that they be co-administered.

Weekly Epidimiological Record, No. 49, 4 December 2009

In view of the public anxieties over vaccine safety that have been reported in the media, SAGE urged that clear messages on the safety of the pandemic (H1N1) 2009 vaccine be communicated to the public and the media.
given the substantially elevated risk for severe outcomes of infection with pandemic (H1N1) 2009 virus in pregnant women, SAGE recommended that, in the absence of a specific contraindication by the regulatory authority or from the WHO prequalification review, any licensed pandemic vaccine can be used to protect pregnant women.
Vaccination with licensed H5N1 vaccine is strongly recommended for laboratory workers involved in the following activities: large-scale production or manipulation of HPAI H5N1 viruses, working with these viruses over a long period, working with HPAI H5N1 viruses that are resistant to licensed antiviral compounds, or working with viruses with the potential for increased transmissibility in mammalian species.

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HIV

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE recognized the importance of activities targeting capacity building and the development of clinical trial sites to ensure that all phases of clinical trials could be conducted in a way that meets the highest scientific, legal, ethical and regulatory standards as well as ensuring that communities are involved in the process. It will be important to develop such sites in developing countries where future vaccines would offer the most benefit.

Recognizing the complex scientific questions that need to be addressed with novel vaccine technologies, SAGE encourages efforts to facilitate close interaction and early discussions between researchers and national regulatory authorities. Additional training of members of national regulatory authorities in scientific aspects should also be included in the training programmes that are being implemented by WHO and other international sponsors.

SAGE expressed its support for the work of WHO in the area of developing vaccines against HIV, TB and malaria in close cooperation with other international and national partners and confirmed the critical role WHO has in developing relevant policies, norms and standards to facilitate the highest scientific, regulatory and ethical standards of clinical trials worldwide.
Influenza

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE recommended that WHO should provide support to developing countries for the development of national, seasonal and pandemic influenza vaccination policies. All countries should develop pandemic preparedness plans that include strategies for the deployment of vaccines when these become available. SAGE stressed that countries must not depend solely on vaccines for pandemic control because lack of vaccine or at best shortage will be a reality in most countries. With the goal of facilitating equitable and timely access, WHO should continue to play a role in advising on priority groups for immunization with pandemic vaccine (http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2004_8/en/index.html).

WHO should provide advice for enhanced surveillance for early detection of new influenza strains and of the onset of a pandemic, if it occurs. WHO should pursue its efforts in strengthening the capability in developing countries of health ministries and national regulatory authorities to facilitate the movement of samples and to ensure prompt registration of pandemic vaccines. Global regulatory convergence should be considered, and WHO should facilitate progress in this direction.

WHO should support research and development for pandemic and seasonal vaccines, including alternative and more effective methods of vaccine delivery such as intradermal and intranasal vaccination, improved vaccines and novel production technologies. SAGE noted that there is currently no influenza vaccine production capacity in the African region. Where appropriate, WHO should facilitate developing countries in establishing local capacity for production of influenza vaccine (including pandemic vaccine) based on manufacturers of vaccines of assured quality and should provide support for relevant technology transfer.

WHO should collaborate with expert groups to model the impact of different vaccination strategies in pandemic control, including the possibility of strategic deployment of vaccines, under various epidemiological settings. The risks and benefits of diverting some current vaccine production facilities to the production of influenza vaccines should be investigated. This should be taken forward urgently by WHO as it may provide a means of expanding vaccine production capacity more effectively than reliance on increasing use of seasonal influenza vaccination. The possible negative impacts on supplies of other vaccines should be considered.

WHO should ensure that the expertise in rapid mobilization for mass immunization is included in influenza preparedness planning. In addition, similar considerations should be given to access and distribution of antiviral medication.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE supported the efforts of WHO to scale up activities relating to influenza pandemic vaccine development, evaluation and capacity building, and the monitoring of seasonal influenza vaccine supply and uptake.
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Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

WHO should ensure that there is unrestricted sharing of samples and vaccine strains internationally.

JE

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE requested the updating of the WHO position paper on JE immunization.

MMR

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

The WHO secretariat should make special efforts to collaborate with industry to increase global availability of MMR vaccines that contain strains of mumps vaccines with the best safety profile.

Measles

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE considered that the GIVS goal of 90% (measles) mortality reduction by 2010 remained appropriate. SAGE recommended that work be undertaken to prepare for discussions on the feasibility of a global elimination goal.
**Meningococcal**

**Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006**

SAGE requested an urgent expert consultation to review all data on the immunogenicity of fractional doses (of meningococcal vaccine.)

SAGE recognizes the imminent threat of epidemic meningitis in the African Region and the serious shortage of vaccine should this scenario unfold. SAGE concluded that in the event of an epidemic and in the context of vaccine shortage, the national authorities of affected countries should undertake a risk-benefit analysis that recognizes the public health benefits of using fractional doses of licensed polyvalent polysaccharide vaccines during mass vaccination campaigns in order to provide protection to a larger proportion of the population. Limiting vaccination to narrower age groups at highest risk (that is, up to the age of 15 years instead of up to age 29) should also be considered.

**Mumps**

**Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006**

SAGE requested that the WHO position paper on mumps vaccines be revised, drawing on the conclusions and recommendations from the recent consultation on use of mumps vaccine in the Eastern Mediterranean Region. The revision should take into consideration the accumulating global experience that high coverage with 2 doses of measlesmumpsrubella vaccine (MMR) is required to effectively prevent mumps outbreaks.

Additional information on the safety of different mumps vaccine strains is available from country experiences with use of mumps vaccine in mass campaigns and routine settings. These data should be reviewed by the GACVS and the resulting conclusions included in the revision of the WHO mumps position paper.
New Vaccines

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE recommended that WHO gives a clear signal on the priority for wider use of pneumococcal vaccine in children.

Lack of clarity of demand is a critical factor inhibiting industrial scaling up of manufacturing capacity. This uncertainty needs to be overcome since validated demand forecasts are essential for the commitments required from industry that will make this vaccine available at affordable prices.

In particular, evidence was required through studies on disease burden of the cost benefit of using pneumococcal conjugate vaccines and the feasibility of vaccine delivery to all vulnerable groups.

Pneumococcal serotype prevalence studies, undertaken in different settings, are required to judge the appropriateness of the conjugate vaccine to be used. A firm position from SAGE will be required once serotype prevalence studies are completed to judge the appropriateness of the conjugate vaccine available.

(SAGE) recognized that a global recommendation, made before resolution of funding and supply issues, could leave vulnerabilities that have been experienced with the implementation of Hib vaccine.
Outbreak Control

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE recommended that WHO should provide support to developing countries for the development of national, seasonal and pandemic influenza vaccination policies. All countries should develop pandemic preparedness plans that include strategies for the deployment of vaccines when these become available. SAGE stressed that countries must not depend solely on vaccines for pandemic control because lack of vaccine or at best shortage will be a reality in most countries. With the goal of facilitating equitable and timely access, WHO should continue to play a role in advising on priority groups for immunization with pandemic vaccine (http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2004_8/en/index.html).

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WHO should ensure that the expertise in rapid mobilization for mass immunization is included in influenza preparedness planning. In addition, similar considerations should be given to access and distribution of antiviral medication.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).
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### Policy

**Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006**

SAGE requested that the WHO position paper on mumps vaccines be revised, drawing on the conclusions and recommendations from the recent consultation on use of mumps vaccine in the Eastern Mediterranean Region. The revision should take into consideration the accumulating global experience that high coverage with 2 doses of measles-mumps-rubella vaccine (MMR) is required to effectively prevent mumps outbreaks.

### Polio

**Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006**

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### Procurement

**Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006**

SAGE supported the efforts of WHO to scale up activities relating to influenza pandemic vaccine development, evaluation and capacity building, and the monitoring of seasonal influenza vaccine supply and uptake.

**Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006**

WHO should ensure that there is unrestricted sharing of samples and vaccine strains internationally.
Program Management

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

SAGE suggested that the GIVS research agenda be expanded beyond clinical trials to include other areas of research, such as health systems research, acceptability and community preparedness studies, epidemiological studies and cost-effectiveness studies.

SAGE praised the overall GIVS costing model and encouraged its further refinement and completion by WHO. Specifically, it was noted that the costing of surveillance and monitoring and for advocacy and communication may have been underestimated.

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Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE requested the updating of the WHO position paper on JE immunization.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE considered that the GIVS goal of 90% (measles) mortality reduction by 2010 remained appropriate. SAGE recommended that work be undertaken to prepare for discussions on the feasibility of a global elimination goal.
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

One non-traditional approach to immunization financing is Advanced Market Commitments (AMCs.) The essence of the AMC mechanism is an agreement made by donors to guarantee a pre-set fixed price for a fixed market size (number of doses) that will be paid for a vaccine that meets a specific pre-established "target product profile"; this guarantee is made with the understanding that the recipient (developing) countries agree to make co-payments to purchase the vaccine.

Once the commitment is exhausted, manufacturers, having benefited from the subsidy, are contractually obliged either to continue to sell to developing countries at a price that the countries can accommodate over the long term or to license their technology to other manufacturers.

Three major roles were identified for WHO: (i) to provide recommendations on target product profiles through SAGE; (ii) to conduct the prequalification process for AMC-eligible products to be purchased through United Nations agencies; and (iii) to provide technical advice on evidence-based decision-making, priority setting, the introduction of new vaccines, and health-system financing to governments of AMC-eligible countries. SAGE recommends that WHO assumes these functions.

During discussion, it was recommended that the target product profile include elements aimed at reducing systems costs (especially related to the cold chain), such as specifying the presentation and vial size.

SAGE endorsed the role that is proposed for it - that is, to review WHO’s proposals for the target product profile and to make a recommendation on the most appropriate profile.

SAGE recommends that the GAVI Alliances secretariat, the World Bank and the AMC independent advisory committee further refine and clarify the AMCs operating mechanisms so that potential obstacles to effective implementation are addressed.

SAGE recommends that more in-depth investigation should be done of the investments in immunization systems required to support the introduction of pneumococcal vaccine in AMC-eligible countries (which are also GAVI-eligible countries). SAGE also recommends that the impact of different copayment scenarios on the immunization financing profiles of AMC-eligible countries should be further modelled and investigated using more accurate estimates of future demands from countries.

Research

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

SAGE recognized the critical role that WHO should play in the international coordination of research and evaluation of influenza pandemic vaccines.
Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

SAGE recognized the importance of activities targeting capacity building and the development of clinical trial sites to ensure that all phases of clinical trials could be conducted in a way that meets the highest scientific, legal, ethical and regulatory standards as well as ensuring that communities are involved in the process. It will be important to develop such sites in developing countries where future vaccines would offer the most benefit.

Recognizing the complex scientific questions that need to be addressed with novel vaccine technologies, SAGE encourages efforts to facilitate close interaction and early discussions between researchers and national regulatory authorities. Additional training of members of national regulatory authorities in scientific aspects should also be included in the training programmes that are being implemented by WHO and other international sponsors.

SAGE expressed its support for the work of WHO in the area of developing vaccines against HIV, TB and malaria in close cooperation with other international and national partners and confirmed the critical role WHO has in developing relevant policies, norms and standards to facilitate the highest scientific, regulatory and ethical standards of clinical trials worldwide.

Schedule

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 9-11 November 2005

(SAGE recognized) that immunization schedules in use today vary greatly around the world, and it is unlikely that a single, uniform immunization schedule would suit all countries. WHO should aim to provide countries with advice on the parameters to be considered when they select a schedule. There was unanimous support for a new review of the evidence base, and agreement that changes in schedule are not appropriate without strong evidence to demonstrate benefit.

SAGE recommended that a review of the issues surrounding the primary schedule, boosters and adolescent vaccination should be undertaken. This should incorporate disease control strategies, immunology, operational aspects of health services (not just vaccination services) and economics.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).
Travellers

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The ACPE (Advisory Committee on Polio Eradication) recommended that the risk of importation from polio-infected areas should be reduced further by ensuring all travellers from such areas are immunized, regardless of their age or immunization status; it proposed that a standing recommendation be established to this effect under the International Health Regulations (IHR) (2005).

VPD Surveillance

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

The global framework (on immunization monitoring and surveillance) describes 2 strategic areas: surveillance for vaccine-preventable diseases and immunization monitoring. The ancillary function of funding surveillance and monitoring is added as a third section.

The vision of the global framework is that, by 2010, there should be an integrated epidemiological, laboratory and programme-monitoring network for the surveillance of vaccine-preventable diseases and monitoring of the performance of immunization programmes. This network will provide high quality information to measure the impact of vaccination and maximize the safe, effective and equitable use of vaccines at country, regional and global levels to reduce or eliminate the burden of vaccine-preventable diseases.

SAGE endorse the global framework documents with some modifications. Modifications suggested included: expanding the linkages to the IHR (International Health Regulations) by providing examples of how some vaccine-preventable diseases fit into the new IHR because they constitute a public health emergency of international health concern; including operational guidance on ways to implement this strategy at the local level in the Way forward section; defining key epidemiological data used in the furtherance of mathematical modelling; and emphasizing recent developments on surveys to monitor programmes and to validate estimates (for example, it is now recommended that Multiple Indicator Cluster Surveys take place every 3 years instead of every 5 years).

SAGE suggests that WHO should produce a clear dissemination plan for the global framework.
Vaccine Quality

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

Additional information on the safety of different mumps vaccine strains is available from country experiences with use of mumps vaccine in mass campaigns and routine settings. These data should be reviewed by the GACVS and the resulting conclusions included in the revision of the WHO mumps position paper.

Conclusions and recommendations from the Strategic Advisory Group of Experts (SAGE) - 10-11 April 2006

The WHO secretariat should make special efforts to collaborate with industry to increase global availability of MMR vaccines that contain strains of mumps vaccines with the best safety profile.