VACCINES AND BIOLOGICALS

THIRD MEETING OF THE STRATEGIC ADVISORY GROUP OF EXPERTS

14-15 JUNE 2001, CICG GENEVA

AGENDA

THURSDAY 14 JUNE 2001- INNOVATION SESSION – SALLE 15 CHAIR : Dr Claire Broome – RAPPORTEUR : Dr Michel Greco - V&B STAFF: Thomas Cherian			
Topic	**Overview of the topic**	**Presenter**	**Time[1]**
Opening	Plenary session to introduce format of meeting – Then the group breaks into three parallel sessions Official opening by Dr Hiro Suzuki , Executive Director HTP	Melgaard Nossal	8:30-9:30
AVI Project	**An overview of the priority project**: The failure to develop new vaccines with developing country needs in mind and to introduce those already developed contributed to the formation of GAVI. The Accelerated Vaccine Introduction (AVI) priority project is an effort to facilitate new vaccines introduction into the developing world. This session provides an overview of the project framework to SAGE and opportunities for substantial input on all aspects of the project.	Dr Wenger	9:30 –10:00
	Disease burden activities: The lack of burden data to guide R&D and vaccine introduction has been widely recognized. In the past two years, there has been progress to conduct standardized burden studies, develop methods to estimate burden and provide various field-friendly tools (costing guidelines, burden study protocols, rapid estimation tools, and impact assessment guidelines). Many gaps however remain. This session will review progress, future plans and gaps.	Dr Nelson	10:00-10:30
	Pneumococcal conjugate and second generation rotavirus vaccines: The GAVI board has targeted Pneumococcal, Rotavirus and meningococcal vaccines for accelerated development and introduction. An agenda is being developed of activities that will be carried out by various partners. This session will focus on WHO role in contributing to this effort.	Dr Ivanoff Dr Cherian	11:00- 11:45
	AVI supply and financing activities and " Combo vaccines": The development of combination vaccines will have far reaching implications with regard to production capacity, supply, financing and programmatic issues. Increased use of combination vaccines as a way to introduce underutilitzed antigens into an immunization programme provides a case study for the programmatic and supply issues facing national immunization managers today.	Ms McKinney	11:45- 12:30
	Global and Regional vaccine introduction activities: V&B is assisting with coordination of technical support for new vaccine introduction, including preparation of generic guidelines for introduction of hepatitis B and Hib vaccines; responding to requests for technical assistance, evaluating current introduction activities, and providing additional manpower to WHO regional offices. The status of these activities will be reviewed.	Dr Wenger	14:00- 14:30
	Elimination of Epidemic Meningitis in Sub-Saharan Africa: To prevent and eliminate epidemic meningococcal disease in the African meningitis belt, WHO and CVP/PATH, have created a partnership to accelerate the development, evaluation and introduction of serogroup A plus C meningococcal conjugate vaccine at an affordable price. This partnership aims at establishing a public/private sector partnership, which can be a model for other developing country market vaccines.	Dr Jodar	14:30- 15:30
R&D Initiatives	**The WHO Initiative for Vaccine Research: interaction with international R&D initiatives:** Vaccine R&D in WHO and UNAIDS has been restructured into the Initiative for Vaccine Research (IVR). The initiative should act as a unified entity, internally as well as with outside partners. How will the IVR strengthen its ties with outside organizations/initiatives such as NIH, EU, CVP, IVI, GAVI R&D task force etc. in order to avoid overlap and achieve synergies.	Dr Aguado	16:00- 17:30

[1] All timings include 1/3 presentation and 2/3 discussion. Coffee Breaks at 10:30-11:00 and 15:30-16:00

THURSDAY 14 JUNE 2001 - IMUNIZATION SYSTEMS SESSION – SALLE 4 CHAIR: Dr Mohammed Ali Jaffer – RAPPORTEUR : Dr Alenka Kraigher – V&B STAFF : U. Kou and C.A. Hoffman			
Topic	**Overview of the topic**	**Presenter**	**Time**
Introduction	Plenary session to introduce format of this year's SAGE , introduction of participants and adoption of agenda- Then the group breaks into three sessions	Dr Melgaard Dr Nossal	8:30-9:30
Immunization systems	**Strengthening immunization services**	Dr Olivé	9:30-10:30
Coverage	**The joint UNICEF/WHO review and update of immunization coverage 1980-1999:** The 1998 SAGE requested that V&B address the completeness and quality of immunization coverage reported to WHO. WHO and UNICEF have been jointly reviewing national immunization from 1980-1999. In some instances estimates were made that vary from previously official reported data. SAGE will be informed of this activity.	Mr Burton	11:00-11:45
Steering committee on immunization safety	The Steering Committee on Immunization Safety at its 2nd meeting (October 2000) reviewed the priority project's activities and made a series of recommendations, with an emphasis on advocacy and partnership building, that will be briefly reported to SAGE. A number of these recommendations and V&B activities relate to the UNICEF-WHO-UNFPA statement that by the end of 2003, all countries should use only auto-disable syringes for immunization.	Dr Kraigher	11:45-12:30
BCG Vaccine – the next ten years	BCG is one of the longest-standing vaccines of immunization, and is still administered in most countries. It has been used to vaccinate millions of infants since its introduction. Although an improved new anti-tuberculous vaccine is under development, and not withstanding the problems beset by continuing its administration, BCG is needed until such a vaccine is tested and available - at least another decade.	Dr Clements	14:00-15:00
Thiomersal and vaccines	Theoretical concerns have been raised over the use of the organomercuric preservative, thiomersal, in vaccines. A policy of elimination, reduction or replacement of thiomersal in paediatric vaccines has implications for vaccine quality, the WHO " multidose vial policy ", and for future vaccine supply. SAGE will be requested to provide policy direction in this area.	Dr Dellepiane	15:00-15:30 16:00-16:30
BSE/TSE and Vaccines	The possibility of transmitting CJD through vaccines, blood and blood products, or other biologicals is causing considerable concern throughout the world in the wake of the appearance of vCJD in the UK following the BSE epidemic in cattle.	Dr Griffiths	16:30-17:30

THURSDAY 14 JUNE 2001- ACCELERATED DISEASE CONTROL SESSION – SALLE 16 CHAIR : Dr Merceline Dahl-Regis - RAPPORTEUR : Dr Prayuna Kunasol - V&B STAFF: D. Wood			
Topic	**Overview of the topic**	**Presenter**	**Time**
Introduction	Plenary session to introduce format of this year's SAGE , introduction of participants and adoption of agenda- Then the group breaks into three sessions	Dr Melgaard Dr Nossal	8:30-9:30
POLIO	**Polio Eradication: Impact of Acceleration & Priorities for 2001-2:** Through acceleration in 1999-2000, reported cases have fallen by 60% with at most 20 endemic countries by 2001. Key targets are (1) achieving <10 endemic countries by end-2001 and (2) interrupting polio worldwide by end-2002. WHO's 2001 priorities are: aggressive mopping-up in all low transmission countries (esp. India, Bangladesh); extra rounds of house-to-house NIDs in high transmission countries (esp. Nigeria, DR Congo, Angola, Pakistan, Afghanistan); and certification-standard surveillance (esp. Ethiopia). The greatest risks to the end-2002 goal are insufficient funding and quality of activities in the above-mentioned countries. **Polio Eradication: OPV Cessation and the Post-Immunization Era:** The Polio TCG will be overseeing a programme of work, supported by a polio research Steering Committee, on (1) when and how to stop OPV after certification of eradication and (2) how to minimize the risk of, and respond to, a polio reintroduction in the post-immunization era. The TCG will eventually recommend strategic options on both of these issues for the consideration/endorsement of SAGE. The concurrence and/or comments of SAGE are needed on this 'endgame' programme of work and the role of SAGE in this process.	Dr Aylward Mr Maher Dr Wood	9:30- 10:30 and 11:00-12:30
MEASLES	**Almost 1 million preventable measles deaths every year:** Measles remains the leading cause of vaccine-preventable child mortality. The remaining disease burden is primarily attributable to the underutilization of the vaccine. WHO/UNICEF's new Strategic Plan is to provide a framework for guiding and coordinating measles mortality reduction efforts. The Strategic Plan seeks to halve measles mortality worldwide. This session will give an overview of the strategic plan and provide SAGE with opportunities to contribute on the best approach for its implementation.	Dr Bilous Regional offices	14:00-15:30
MNT	By the year 2000, 104 countries had achieved maternal and neonatal tetanus elimination but 57 had not. A new joint UNICEF, WHO, UNFPA initiative has been launched to achieve and sustain MNT elimination by the year 2005. The session will review the components of the plan and some of the specific challenge approach to achieving it.	Dr Gasse Dr Birmingham	16:00-16:45
VITAMIN A	**Vitamin A Supplementation and Immunization Activities:** Vitamin A deficiency (VAD) affects an estimated 140 to 250 million preschool children globally. Currently vitamin A supplementation is provided to vulnerable children through linking vitamin A delivery with polio eradication activities and other supplemental immunization campaigns. With the gradual phasing-out of polio NIDs, there is a need to ensure longer-term sustainability and potentially greater health impact by linking vitamin A supplementation with routine immunization contacts.	Ms Mathews	17:00 17:30

FRIDAY 15 JUNE 2001- PLENARY SESSION – SALLE 4 CHAIR : Dr Guss Nossal - RAPPORTEUR: Dr Peter Folb – V&B STAFF: J. Milstien, N. Dellepiane			
Topic	**Overview of the topic**	**Presenter**	**Time**
Open plenary session	20 minutes report by each one of the chairs of the first day's parallel sessions. Focus on main issues for SAGE decision and recommendations	Committees chairs/	8:30-10:00
GAVI	Provide SAGE with general feedback on GAVI process and challenges faced. Discuss issues raised with the process by Regions and countries. Give an opportunity to SAGE to have an overview of the GAVI initiative and make recommendations which could then be forwarded to DG and the GAVI board	Mr Zaffran	10:00-10:30 and 11:00-11:30
GAVI and Accelerated Disease Control Initiatives	At the request of the GAVI Board, the feasibility of aligning GAVI objectives with the accelerated disease control initiatives has been investigated. The implications, both positive and negative, of various scenarios have been elaborated through a consultative process with partners and the GAVI Working Group. This analysis will be presented the GAVI Board Meeting, June 21-22, 2001	Ms Goodman	11:30- 12:30
Vaccine selection: Implication of two tracks	There appears to be a divergence of products in national immunization programmes between developing and industrialized countries. In developing countries, the antigens are BCG, combinations based on whole cell pertussis, oral polio vaccine and monovalent measles vaccine, while industrialized countries may have stopped BCG, and use combinations based on acellular pertussis vaccines, inactivated polio vaccine and MMR. In addition, the trend is to single dose presentations in industrialized countries, while multidose products are the rule in the developing world. SAGE is asked to consider this divergence, its potential impact on supply, type of suppliers, price, vaccine regulation, and, eventually, choice of vaccines for national immunization programmes.	Dr Milstien	14:00- 14:45
Yellow Fever vaccine: Issues in its uptake	YF has been an "orphan" disease for years despite the fact that it has been recommended in countries at risk for 10 years. An inexpensive, safe and effective vaccine has been available, but with lack of use more and more manufacturers have left production, and we have only one large scale supplier. This results in large threat of urban outbreaks and no vaccines either for the new GAVI initiative to get YF incorporated. The topic will cover problems, issues, potential solutions, and lessons learned.	Dr Avokey Dr Oliva	14:45- 15:30
Global advisory committee on vaccine safety	The Global Advisory Committee on Vaccine Safety (GACVS) was set up as a technical advisory body to provide WHO with independent scientific assessment of vaccine safety issues. It met twice in 2000 and discussed: (i) the relationship between macrophagic myofasciitis and injection of aluminium-containing; (ii) the risk of auto-immune diseases; (iii) the health effects of thiomersal-containing vaccines, and (iv) the issue of child survival following routine vaccination and purported negative impact of DPT on infant survival . This latter issue will be the focus of this discussion.	Dr Folb, Dr Griffin	16:00-17:00
Wrap up	Review of main conclusions and recommendations	Dr Nossal	17:00-18:00

V&B SAGE : PROPOSED ASSIGNMENT OF SAGE MEMBERS FOR THE 14 JUNE 2001 PARALLEL SESSIONS

MEMBER	INNOVATION	IMMUNIZATION SYSTEMS	ACCELERATED DISEASE CONTROL
Dr M. S. Ali Jaffer		**CHAIR**	
Ms M. Allies		**X**	
Dr I. Arita			**X**
Dr C. Broome	**CHAIR**		
Dr M. Burgess	**X**		
Dr M. Dahl-Regis			**CHAIR**
Dr P. Folb		**X**	
Dr M.Greco	**RAPPORTEUR**		
Dr A. Kraigher		**RAPPORTEUR**	
Dr P. Kunasol			**RAPPORTEUR**
Dr J. La Montagne	**X**		
Dr P. Makela	**X**		
Prof. F. Nkrumah			**X**
Sir G. Nossal	**X**		
Dr L. Slamet		**X**	
Dr H. Triki			**X**
Dr J. Yunes			**X**
Dr K. Zoon		**X**	