

## <u>Agenda</u>

## Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 17 - 19 October 2017

## Executive Board Room, WHO Headquarters, Geneva, Switzerland

Tuesday, 17 October 2017

Time	Session	Purpose of session, target outcomes and questions for SAGE	Duration
8:30	Welcome – introduction of participants		20 min.
	A. Cravioto, Chair of SAGE.		
8:50	Report from Director, IVB - Session 1	FOR INFORMATION	1h 30 min.
	Global report including key updates and challenges from regions. JM. Okwo-Bele, WHO. 30 min.		
	Discussion: 1h		
10:20	Coffee/Tea break	Break	30 min.
10:50	Report from Gavi, the Vaccine Alliance - Session 2	FOR INFORMATION	30 min.
	Report from Gavi, the Vaccine Alliance. S. Berkley, Gavi, the Vaccine Alliance. 15 min.		
	Discussion: 15 min.		
11:20	Reports from other Advisory Committees on Immunization – Session 3	FOR INFORMATION	1h
	Global Advisory Committee on Vaccine Safety (GACVS). R. Pless, Chair of GACVS. 10 min.		
	Discussion: 10 min.		
	Product Development for Vaccines Advisory Committee (PDVAC). D. Kaslow, Chair of PDVAC. 10 min.		
	Discussion: 10 min.		

	Immunization and Vaccines related Implementation Research Advisory Committee		
	(IVIR-AC). P. Beutels, IVIR-AC. 10 min.		
	Discussion: 10 min.		
12:20	Lunch	Break	1h 30 min.
13:50	Typhoid vaccines - Session 4	FOR DECISION	2h
	Introduction. I. Jani, Chair of SAGE Working Group on Typhoid Vaccines. 5 min.  Overview of the epidemiology and global disease burden of typhoid fever. J. Crump, Member of SAGE Working Group on Typhoid Vaccines. 15 min.  Current control strategies, antimicrobial resistance of <i>S.</i> Typhi and implications for typhoid control. Z. Bhutta, Member of SAGE Working Group on Typhoid Vaccines. 15 min.  Discussion: 20 min.  Evidence review on the immunogenicity, efficacy/effectiveness and safety of typhoid conjugate vaccines. M. Levine, Member of SAGE Working Group on Typhoid Vaccines. 20 min.  Conclusions and proposed recommendations of the SAGE Working Group on Typhoid Vaccines. I. Jani, Chair of SAGE Working Group on Typhoid Vaccines. 15 min.  Discussion: 30 min.	<ul> <li>Present SAGE with the report of the SAGE Working Group on Typhoid Vaccines, including:</li> <li>The evidence review on disease and economic burden, increasing threat of antimicrobial resistance (AMR) and effectiveness and safety of typhoid vaccines.</li> <li>Draft recommendations on vaccine use for typhoid control (in context of other interventions), with a focus on newly licensed typhoid conjugate vaccines, as well as an update on the currently recommended Vi polysaccharide (ViPS) and Ty21a vaccines.</li> <li>Updated SAGE recommendations on typhoid vaccine use will be used to update the 2008 WHO position paper on typhoid vaccines.</li> </ul>	
15:50	Coffee/tea break	Break	30 min.
16:20	Polio eradication initiative - Session 5	FOR INFORMATION AND DECISION	2h 30 min.
	Overview of Global Polio Eradication Initiative. M. Zaffran, WHO. 25 min.  Risk assessment and prioritization of Inactivated polio vaccine (IPV) supply and implementation of fractional IPV (fIPV) in the routine immunization. D. Chang Blanc, WHO. 20 min.  Post certification strategy (PCS). B. Burkholder. 15 min.  Report from SAGE Polio Working Group. Y. AL-Mazrou, Chair of the SAGE Polio Working Group. 20 min.	<ul> <li>For information         <ul> <li>To update SAGE on:</li> <li>The current status of the polio eradication program, including the IPV supply situation, risk assessment of types 1 and 3 before bivalent oral polio vaccine (bOPV) withdrawal and the post certification strategy.</li> <li>The status of implementation of fractional IPV in the routine immunization.</li> <li>The preliminary discussions on assessment criteria for OPV withdrawal.</li> </ul> </li> </ul>	
	Discussion: 70 min.	For decision To seek SAGE's recommendations on:	

		<ul> <li>Proposed approach to prioritize IPV allocation in tier 3 and 4 countries, based on the risk ranking.</li> <li>IPV catch-up for children in countries which delayed the introduction of IPV or had stock out due to supply shortage.</li> </ul>	
18:50	End of Day		
19:00	Cocktail		

:00	sday, 18 October 2017 Global Vaccine Action Plan (GVAP): Progress report - Session 6	FOR DECISION	3h
	Update from the GVAP Secretariat, including on the 2017 World Health Assembly 70.14 Global Vaccine Action Plan resolution. T. Cherian (on behalf of the Secretariat of the SAGE Decade of Vaccines Working Group), WHO. 10 min.  Summary of GVAP implementation progress review and recommendations for corrective actions. N. MacDonald, Chair of SAGE Decade of Vaccines Working Group. 30 min.  Discussion:1h 20min.  Immunization related Sustainable Development Goals indicator options and proposal retained by the Decade of Vaccines Working Group. N. Arora, Member of SAGE Decade of Vaccines Working Group. 10 min.  Discussion: 20 min.	SAGE will be expected to produce an independent annual report on progress with the Decade of Vaccines Global Vaccine Action Plan.  Specially, SAGE will be asked to:  Review the DoV WG "Assessment report on DoV progress 2017" based on the "GVAP Secretariat report 2017", regional reports on the implementation of regional vaccine action plans, priority country reports and some independent stakeholder submissions.  Make recommendations on any necessary changes to the formulation of the indicators, operational definitions and/or the processes for data collection.  Identify successes, challenges and areas where additional efforts or corrective actions by countries, regions, partners, donor agencies or other parties, are needed.	
	Presentation of the proposed process to develop a Global Immunization Strategy 2021-2030. C. Mantel, on behalf of WHO. 10 min.  Discussion: 20 min.	Provide recommendations and corrective actions for Member States, regions, partners, donor agencies "SAGE Assessment report on the Decade of Vaccines progress" which will be the basis of the "progress report" for the 2018 WHO Executive Board and World Health Assembly.  Review the immunization related indicators proposed as part of the Sustainable Development Goals indicator and make a final decision on these indicators.  SAGE will further be presented with the preliminary plans for Global Immunization Strategy 2021-30.	
0:00	Coffee/tea break	Break	30 min.
0:30	Global Vaccine Action Plan (GVAP): Progress report, contd.		

11:30	Report of activities from international immunization partners – Session 7	FOR INFORMATION AND DISCUSSION	1h 20 min.
	Developing Country Vaccine Manufacturers Network (DCVMN). S. Prasad, Bharat Biotech International on behalf of DCVMN. 20 min.	Continuation of the series of presentations initiated in October 2015 to be held at SAGE meetings on the immunization-related activities of partners working in the field of immunization.	
	Discussion: 20 min.		
	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). L. Bigger, IFPMA. 20 min.		
	Discussion: 20 min.		
12:50	Lunch	Break	1h
13:50	Rabies vaccines - Session 8	FOR DECISION	3h
	Overview of the global rabies situation. B. Abela-Ridder, WHO. 10 min.	Based on the evidence presented, SAGE is expected to review and endorse draft recommendations related to the following questions:	
	Presentation of evidence on vaccination for pre-exposure rabies prophylaxis (PREP) (Question 1,2,3,4). A. Tarantola, Member of SAGE Rabies Working Group. 15 min.	<b>Question 1:</b> Does novel evidence support the use of PREP in particular sub-populations, apart from persons bearing an occupational rabies exposure risk?	
	Conclusions and proposed recommendations. K. O'Brien, Chair of the SAGE Rabies Working Group. 10 min.	<b>Question 2:</b> Does novel evidence support the need for rabies booster doses in persons at continual or frequent risk of occupational rabies exposure?	
	Discussion: 30 min.	<b>Question 3:</b> Can the duration of the entire course of current PREP regimens be reduced while maintaining immunogenicity and clinical protection?	
	Presentation of evidence on vaccination for post-exposure rabies prophylaxis (PEP) (Question 5,6,7,8,9). A. Tarantola, Member of SAGE Rabies Working Group. 20 min.	Question 4: Can the number of doses administered in current PREP regimens be reduced while maintaining immunogenicity and	
	Conclusions and proposed recommendations. K. O'Brien, Chair of the SAGE Rabies Working Group. 10 min.	clinical protection? <b>Question 5:</b> Which (operational) parameters affect costeffectiveness of intradermal (ID) compared to intramuscular (IM)	
	Discussion: 30 min.	administration route of PEP? a. in urban settings; b. in rural	
	Presentation of evidence on rabies immunoglobulins (RIG) for PEP (Questions 10,11,12,13,14). A. Tarantola, Member of SAGE Rabies Working Group. 15 min.	settings. <b>Question 6:</b> Can the duration of the entire course of current PEP regimens be reduced while maintaining immunogenicity and clinical protection?	
	Conclusions and proposed recommendations. K. O'Brien, Chair of the SAGE Rabies Working Group. 10 min.	<b>Question 7:</b> Can the number of doses administered in current PEP regimens be reduced while maintaining immunogenicity and clinical	
	Discussion: 30 min.	protection?  Question 8: Does novel evidence support recommendations on modified PEP protocols vs current PEP protocols for specific risk	
		groups of rabies exposed patients, such as: Immuno-compromised patients (e.g. HIV-infected); patients concurrently using antimalarial	

		drugs; pregnant women; bat exposures (i.e. for bat lyssavirus)?	
		<b>Question 9:</b> Does a change in route of administration (IM or ID)	
		during a single course of a PEP regimen affect immunogenicity of	
		PEP?	
		<b>Question 10:</b> Are there novel approaches to RIG (-sparing)	
		injection vs current practice as part of PEP for category III exposed	
		patients?	
		<b>Question 11:</b> Is there clinical equivalence in the safe use of eRIG	
		compared to hRIG in category III exposed patients?	
		<b>Question 12:</b> Is there clinical equivalence in the efficacious use of	
		eRIG compared to hRIG in category III exposed patients?	
		Question 13: Can monoclonal antibodies be safely and	
		efficaciously administered in category III exposed patients	
		compared to standard RIG?	
		Question 14: In cases of RIG shortage and constraints, can	
		subcategories of patients be identified who should be given highest	
		priority for RIG administration?	
16:50	Coffee/tea break	Break	30 min.
17:20	Pneumococcal conjugate vaccines (PCV) - Session 9	FOR INFORMATION AND DECISION	2h
	Introduction. A. Pollard, Chair of the PCV Working Group. 2 min.	SAGE will be expected to review evidence related to the following questions and update recommendations on the use of	
	Constitution of DCV		
	Current status of PCV usage and current recommendations. K. O'Brien, SAGE PCV	Pneumococcal conjugate vaccines accordingly:	
	Current status of PCV usage and current recommendations. K. O'Brien, SAGE PCV Working Group member. 10 min.		
	Working Group member. 10 min.	Pneumococcal conjugate vaccines accordingly:	
	Working Group member. 10 min.  Review of PRIME systematic review. M. Knoll, Johns Hopkins Bloomberg School of	Pneumococcal conjugate vaccines accordingly:  1) In the general population, what overall effectiveness and impact does a 2p+1 PCV dosing schedule elicit as compared to a 3p+0 PCV dosing schedule?	
	Working Group member. 10 min.	Pneumococcal conjugate vaccines accordingly:  1) In the general population, what overall effectiveness and impact does a 2p+1 PCV dosing schedule elicit as compared to a 3p+0 PCV dosing schedule?  2) In the general population, what overall effectiveness and	
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	Working Group member. 10 min.  Review of PRIME systematic review. M. Knoll, Johns Hopkins Bloomberg School of Public Health. 35 min.  Review of modelling on catch-up immunization. S. Flasche, London School of	Pneumococcal conjugate vaccines accordingly:  1) In the general population, what overall effectiveness and impact does a 2p+1 PCV dosing schedule elicit as compared to a 3p+0 PCV dosing schedule?  2) In the general population, what overall effectiveness and impact does PCV10 elicit as compared to PCV13?  3) In the general population, what additional value does	
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	Working Group member. 10 min.  Review of PRIME systematic review. M. Knoll, Johns Hopkins Bloomberg School of Public Health. 35 min.  Review of modelling on catch-up immunization. S. Flasche, London School of Hygiene and Tropical Medicine. 10 min.	Pneumococcal conjugate vaccines accordingly:  1) In the general population, what overall effectiveness and impact does a 2p+1 PCV dosing schedule elicit as compared to a 3p+0 PCV dosing schedule?  2) In the general population, what overall effectiveness and impact does PCV10 elicit as compared to PCV13?  3) In the general population, what additional value does catch-up vaccination with 1 or 2 doses of PCV in vaccinenaïve children above the birth cohort have as compared	
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Thursday, 19 October 2017

08:00	Measles and rubella elimination – Session 10	FOR INFORMATION AND DECISION	2h 45 min.
	Introduction. N. Turner, Chair of the SAGE Measles and Rubella Working Group. 5 min.  Global update and progress on the implementation of recommendations from the midterm review. A. Dabbagh, WHO. 20 min.	For information:     Global update on measles and rubella     Progress on the implementation of recommendations from the midterm review.	
	Discussion: 30 min.  Critical immunity threshold for measles elimination. S. Funk, London School of Hygiene and Tropical Medicine. 20 min.  Discussion: 20 min.  Measles in infants less than 6 months of age and effectiveness and safety of vaccination. N. Crowcroft, Member of SAGE Measles and Rubella Working Group. 25 min.	<ul> <li>For recommendations on: <ul> <li>Global criteria for country categorization.</li> <li>What level of population immunity is needed to achieve herd immunity (age-specific immunity thresholds).</li> <li>The possibility and eventual need to vaccinate infants less than 6 months of age.</li> <li>Review evidence and provide policy guidance related to revaccination of HIV infected adults.</li> </ul> </li> </ul>	
	Discussion: 20 min.		
10:20	Coffee/tea break		
	•	Break	30 min.
10:50	Measles and rubella elimination –Session 10, contd.  Revaccination of HIV infected adults. W. Moss, Member of SAGE Measles and Rubella Working Group. 10 min.  Discussion: 15 min.	Break	30 min.
	Measles and rubella elimination –Session 10, contd.  Revaccination of HIV infected adults. W. Moss, Member of SAGE Measles and Rubella Working Group. 10 min.	FOR DECISION	<b>30 min.</b> 2h 20 min.
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10:50	Measles and rubella elimination –Session 10, contd.  Revaccination of HIV infected adults. W. Moss, Member of SAGE Measles and Rubella Working Group. 10 min.  Discussion: 15 min.  Bacille Calmette-Guérin (BCG) vaccines -Session 11  Introduction	FOR DECISION  Present SAGE with the report of the SAGE BCG Working Group and	

## 19 October 2017

	Conclusions and proposed recommendations. C. Wiysonge, Chair of the SAGE BCG Working Group. 20 min.  Discussion: 1h 10 min	
13:35	Closing	20 min.
13:55	End of meeting	