

Department of Immunization, Vaccines and Biologicals (IVB)



SLIDE DECKS

Strategic Advisory Group of Experts on Immunization 4-8 October 2021

Virtual meeting, WHO Geneva, Switzerland

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Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 4-8 October 2021 Virtual Meeting Draft Agenda

Day 1: SAGE meeting

Monday, 4 October 2021

10:00	Closed SAGE meeting	Preparation of the sessions of the day.	1h
11:00	Break	Break	15 min.
11:15	Opening and welcome – introduction of participants Director-General A. CRAVIOTO. Chair of SAGE	Opening of the Plenary Meeting	15 min.
11:30	Global and Regional Reports - Session 1	FOR INFORMATION	2h 45 min.
È	Report from the Director of IVB. K. O'BRIEN. WHO. 20 min.		7
	Reports from the Regions – including impact of the COVID-19 pandemic and COVID-19 vaccination on immunization services. WHO. 1h.	APRO PARIO EMIRO EURO SEARO WPRO Image: Constraint of the search of the se	
F	Update from Gavi. S. BERKLEY. GAVI. 10 min.		
F	Update on COVID-19 Global Vaccine Strategy. T. CERNUSCHI. WHO. 15 min.		
	Discussion. 1h.		
14:15	Break	Break	30 min.
14:45	 Monitoring IA2030/Zero dose children/Immunization during and post- COVID-19 pandemic- Session 2 Global immunization - opportunities and challenges for the decade ahead; presentation of the IA2030 2019 baseline and 2020 data. A. LINDSTRAND. WHO. 15 min. IA2030 implementation progress, including IA2030 M&E Framework. A. LINDSTRAND. WHO/E. MAST. CDC. 10 min. Expected role of SAGE within the IA2030 partnership model. A. LINDSTRAND. WHO. 10 min. Discussion. 55 min. 	 FOR RECOMMENDATION Purpose of the session: Present a summary of global immunization data, the IA2030 Monitoring and Evaluation baseline from 2019 and the impact of the pandemic in 2020 and to provide insights into opportunities and challenges for the decade ahead Share IA2030 implementation progress; Regional IA2030 plans, M&E, Ownership and accountability and the learning agenda Propose the expected role of SAGE within the IA2030 partnership model Receive feedback from SAGE on: Reported data and key assessment of global immunization progress from 2019 and 2020 IA2030 implementation progress, including IA2030 structures, reporting and decision-making mechanisms, communications, regional and country immunization programme implementation, and the IA2030 Learning Agenda Role and associated processes for SAGE to provide Independent Technical Review of IA2030 	1h 30 min.

progress and provide recommendations to the IAPC, IA2030 working groups, and to regions and countries

16:15 End of the day

Day 2: SAGE meeting

Tuesday	Tuesday, 5 October 2021				
10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 1. Other important discussion items.	1h		
11:00	Break	Break	15 min.		
11:15	Polio - Session 3	FOR RECOMMENDATION	1h 30 min.		
東	Update from the Global Polio Eradication Initiative. A. O'LEARY. WHO. 10 min. Questions: 10 min.	SAGE will be informed on the current status of the polio eradication program; and launch of the new polio eradication strategy			
束	IPV only schedule options, including Hexavalent vaccine H. VERMA. WHO. 10 min.	SAGE will be asked to review and consider for endorsement:			
Ŕ	Questions: 5 min. Update on nOPV2 first use, clinical development, assessment of safety data and transition from initial to wider nOPV2 use. S. ZIPURSKY, G. MACKLIN and O. MACH. WHO; A. BANDYOPADHYAY. BMGF. 20 min. Questions: 10 min.	 WG's recommendation on IPV only schedules including Hexavalent schedules in polio program. WG's recommendation on transition from initial to wider nOPV2 use based on GACVS safety data assessment. 			
束	Report from SAGE Polio Working Group including I. JANI. SAGE Member. 15 min. Discussion: 10 min.				
12:45	Break	Break	30 min.		
13:15	COVID-19 vaccines – Session 4	FOR RECOMMENDATION	1h 30 min.		
	PART 1- Bharat Biotech COVID-19 vaccine				
京 京	Introduction, session objective setting, update on regulatory decisions and overview of Working Group deliverables. H. NOHYNEK. SAGE member. 5 min. Vaccine safety and efficacy data emerging from Bharat Biotech COVID-19 vaccine clinical trials (phase 1-3 trial results and post marketing). Risk management plans and other implementation considerations. (R. ELLA) COMPANY PRESENTATION. 25 min.	Objectives for this session: Presentation of clinical data on Covaxin [™] from phase 1, 2, 3 and post marketing studies on safety, immunogenicity, efficacy and effectiveness. Outline of ongoing and planned studies on safety and effectiveness. Update on global, regional and country level plans for vaccine safety monitoring.			
	Questions: 15 min Assessment of Evidence, draft recommendations and discussion (SAGE working group). H. NOHYNEK.	Presentation of the assessment of the SAGE working group on the available evidences and the strength of evidences on the questions of the evidence to decision tables.			
	SAGE Member, R. HELFAND, S. DESAI. 35 min.	Based on the presented evidences, presentation of draft recommendations on the use of Bharat Biotech vaccine in priority populations.			

14:45	COVID-19 vaccines – Session 4	FOR DISCUSSION AND RECOMMENDATION	2h
	PART 2 – The need for additional COVID-19 vaccine doses	Objective of the session:	
È	Session objective setting. H. NOHYNEK Definition of "additional dose". D. KASLOW 10 min.	This first session on the topic of additional doses of COVID-19 vaccines will focus on the need for additional COVID-19 vaccine doses in	
Ŗ	Review of evidence on the need for an additional COVID-19 vaccine dose in immunocompromised individuals. S. KOCHHAR, SAGE member, K. TALBOT, E. PARKER. 25 min.	immunocompromised individuals.	
平下	Presentation of draft recommendations. H. NOHYNEK 15 min. Review of evidence on the need for a third dose for inactivated COVID-19 vaccines. D.KASLOW, D.FEIKIN 20 min Draft recommendations and discussion. H.NOHYNEK. 20 min	TENTATIVE SAGE will further be presented with the available evidence to address the issue of providing an additional inactivated vaccine dose In the context of a rapidly changing environment with important data gaps, SAGE will be asked whether the evidence to date are sufficient to provide policy updates on the beforementioned topics.	
16:45	End of the day		
10:45			

Day 3: Joint meeting of SAGE and the Malaria Policy Advisory Group (MPAG)

Wednesday, 6 October 2021

Time	Session	Purpose of session, target outcomes and questions for SAGE	Duration
10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 2. Other important discussion items.	1h
11:00	Break	Break	15 min.
11:15	Opening and welcome of joint session P. ALONSO, K O'BRIEN, WHO. 5 min. A. CRAVIOTO. Chair of SAGE and D. WIRTH. Chair of MPAG. 5 min.	Opening of the Plenary Meeting	10 min.
11: 30	Malaria vaccine - Session 5 (JOINT SESSION SAGE and MPAG)	FOR RECOMMENDATION	1h 30 min.
F	Introduction to the session, Framework for WHO recommendation on RTS,S/AS01 malaria vaccine and summary findings. K. MULHOLLAND. SAGE Member. 5 min.	with updated evidence on feasibility, impact and safety of the RTS,S/AS01 malaria vaccine and the proposed recommendations of the Malaria Vaccine Implementation Programme Advisory Group (MVIP PAG).	
束	Malaria disease burden, epidemiology, status of malaria control and surveillance, and the need for new interventions. D. SCHELLENBERG. WHO. 5 min.	SAGE and MPAG are requested to address the following question:Does the additional evidence on the feasibility, safety and impact of the	
束	Overview of evidence as of 2015 leading to WHO pilot recommendation, remaining key questions and the Malaria Vaccine Implementation Programme (MVIP) M. HAMEL. WHO. 10 min.	RTS,S/AS01 vaccine support a WHO recommendation for use of the vaccine in children in sub-Saharan Africa beyond the current pilot implementation?	
Þ	<i>Addressing outstanding question 1: Feasibility</i> Malaria vaccine implementation experience. R. JALANG'O. National Vaccines and Immunization Programme, Kenya. 10 min.	The SAGE/MPAG recommendations will then be used to update the WHO position paper on the use of a malaria vaccine.	
F	Summary of feasibility evidence. P. NJUGUNA. WHO. 15 min.		



Addressing outstanding question 2: Impact Summary of impact evidence. P. MILLIGAN. LSHTM. 10 min.

Comments & questions: 20 min.

13:00	Break	Break	15 min.
13:15	Malaria vaccine, contd Session 5 (JOINT SESSION SAGE and MPAG)	FOR RECOMMENDATION	2h min.
È	Addressing outstanding question 3: Safety Summary of safety evidence and assessment by the MVIP Data Safety and Monitoring Board (DSMB). C. WHITNEY. Chair of MVIP DSMB. 15 min.	The purpose is to present SAGE and MPAG with updated evidence on feasibility, impact and safety of the RTS,S/AS01 malaria vaccine and the proposed recommendations of the RTS,S SAGE/MPAG Working Group.	
	Comments & questions: 25 min	SAGE and MPAG are requested to address the following question:	
Ŕ	RTS,S SAGE/MPAG Working Group assessment and proposed recommendations. P. SMITH and E. MACETE, Chair and Co-Chair of RTS,S SAGE MPAG Working Group. 15 min. Discussion and formulation of recommendation:	• Does the additional evidence on the feasibility, safety and impact of the RTS,S/AS01 vaccine support a WHO recommendation for use of the vaccine in children in sub-Saharan Africa beyond the current pilot implementation?	
	Closing remarks. D. WIRTH. Chair of MPAG, and A. CRAVIOTO, Chair of SAGE. 5 min.	The SAGE/MPAG recommendations will then be used to update the WHO position paper on the use of a malaria vaccine.	
15:15	Break	Break	15 min.
4			30 min
15:30	Closed SAGE/MPAG meeting		50 mm.
16:00	End of the day		

Day 4: SAGE meeting

Thursday, 7 October 2021

Time	Session	Purpose of session, target outcomes and questions for SAGE	Duration
10:00	Closed SAGE meeting	Preparation of the sessions of the day. Recap of day 3. Other important discussion items.	1h
11:00	Break	Break	15 min.
11:15	Influenza vaccine - Session 6	FOR RECOMMENDATION	1h 30 min.
F	Introduction. A. POLLARD. SAGE member. 5 min. Review of the evidence on the effects of prior	The purpose of the influenza session is to seek SAGE advice on the revision of the global policy on the use of seasonal influenza vaccines and the subsequent update of the WHO position	
曱	influenza vaccines. S. SULLIVAN. WHO Collaborating Centre for Reference and Research on Influenza, Australia. 10 min. Questions: 5 min.	paper on influenza vaccines. SAGE will specifically be asked for its advice on the following issues that are tentatively proposed by the SAGE Working Group on	
Ŕ	Review of the evidence on the effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines. C. CHADWICK. 10 min. Questions: 5 min.	 Influenza as requiring specifics Revision of the target groups previously identified in the 2012 WHO position paper on 	
廩	Review of the evidence for target groups for seasonal influenza vaccination. B. WARSHAWSKY. Public Health Agency of Canada. 15 min. Questions: 5 min.	 Impact of repeat influenza vaccination; Effectiveness of quadrivalent influenza vaccines versus trivalent influenza vaccines; and Research priorities. 	
	Presentation of draft recommendations. A. POLLARD. SAGE member. 15 min.		
	Discussion: 20 min.		
12:45	Break	Break	30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7	Break FOR RECOMMENDATION	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min.	Break FOR RECOMMENDATION Questions posed to SAGE: Does SAGE have any feedback on the	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min.	Break FOR RECOMMENDATION Questions posed to SAGE: - Does SAGE have any feedback on the findings and considerations put forward? - Are there any added resources or methods which should be incorporated?	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min. Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 5 min.	Break FOR RECOMMENDATION Questions posed to SAGE: - Does SAGE have any feedback on the findings and considerations put forward? - Are there any added resources or methods which should be incorporated? - What recommendations can be put forward to Member States?	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min. Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 5 min. Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford, UK. 10 min.	Break FOR RECOMMENDATION Questions posed to SAGE: - Does SAGE have any feedback on the findings and considerations put forward? - Are there any added resources or methods which should be incorporated? - What recommendations can be put forward to Member States?	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min. Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 5 min. Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford, UK. 10 min. Operational considerations: guidance and support to Member States to gather and use data for evidence-based implementation. L. MENNING. WHO. 10 min.	Break FOR RECOMMENDATION Questions posed to SAGE: - Does SAGE have any feedback on the findings and considerations put forward? - Are there any added resources or methods which should be incorporated? - What recommendations can be put forward to Member States?	30 min. 1h 30 min.
12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min. Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 5 min. Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford, UK. 10 min. Operational considerations: guidance and support to Member States to gather and use data for evidence-based implementation. L. MENNING. WHO. 10 min. Draft recommendations for consideration by SAGE. N. MACDONALD. SAGE member. 5 min.	Break FOR RECOMMENDATION Questions posed to SAGE: - Does SAGE have any feedback on the findings and considerations put forward? - Are there any added resources or methods which should be incorporated? - What recommendations can be put forward to Member States?	30 min. 1h 30 min.
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12:45 13:15	Break Behavioural and social drivers of vaccine uptake- Session 7 Introduction and framing. N. MACDONALD. SAGE member. 5 min. Overview of objectives and process to gather and translate evidence. J. LEASK. Univ. of Sydney, Australia. 10 min. Measures: validation of tools and identification of core indicators. N. BREWER. University of North Carolina, USA. 5 min. Interventions: review to identify interventions to increase uptake. C. HENEGHAN. University of Oxford, UK. 10 min. Operational considerations: guidance and support to Member States to gather and use data for evidence-based implementation. L. MENNING. WHO. 10 min. Draft recommendations for consideration by SAGE. N. MACDONALD. SAGE member. 5 min. Q&A and discussion. 45 min. Hepatitis E vaccines- Session 8	Break FOR RECOMMENDATION Questions posed to SAGE: Does SAGE have any feedback on the findings and considerations put forward? Are there any added resources or methods which should be incorporated? What recommendations can be put forward to Member States? FOR INFORMATION AND DISCUSSION	30 min. 1h 30 min. 1



Day 5: SAGE meeting

Friday, 8 October 2021			
12:00	Closed SAGE meeting: wrap up	Recap of day 4. Other important discussion items. Meeting wrap up.	2h 30 min.
14:30	End of final closed meeting		