Meeting of Strategic Advisory Group of Experts (SAGE) on Immunization, 25–27 April 2017

DECLARATION OF INTERESTS

All 15 SAGE members participating in the meeting updated their declaration of interest ahead of the meeting. Eight SAGE members reported relevant interests. One interest was assessed to constitute a conflict of interest in relation to the National Immunization Technical Advisory Group session. Therefore, Charles Wiysonge will recuse himself from participating in the discussion and any potential decision-making in relation with this session. It was concluded that all other members could fully participate in all sessions. All the reported relevant interests are summarized below:

Ilesh Jani:

- Serves as a site principal investigator for a clinical trial evaluating the safety, tolerability and immunogenicity of two prime-boost regimens of the candidate prophylactic vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo funded by Janssen Vaccines & Prevention B.V., and the Joint Vaccine Acquisition Program (JVAP). This interest was assessed as non-personal, specific and financially significant*.
- Serves as principal investigator for phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection in women in sub-Saharan Africa funded by the US National Institutes of Health (NIH), the HIV Vaccine Trial Network (HVTN) and the U.S. Military HIV Research Program (MHRP). This interest was assessed as non-personal, non-specific and financially significant*.

Firdausi Quadri:

- Serves as a principal investigator for a trial evaluating the introduction of cholera vaccine in Bangladesh funded by the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, specific and financially significant*.
- Serves as principal investigator for a randomized, placebo-controlled trial to measure the protection conferred by a single dose regimen of bivalent, killed, whole cell oral cholera vaccine (Shanchol) in Dhaka, Bangladesh funded by the International Vaccine Institute and the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, specific and financially significant*.
- Serves as principal investigator for a phase I/II dose-escalation study to evaluate safety, tolerability and immunogenicity of '2-dose primary series' single strain (Hikojima serotype) inactivated Oral Cholera Vaccine formulations funded by MSD, Wellcome Trust and Hilleman Laboratories. This interest was assessed as non-personal, specific and financially significant*.
- Serves as a co-principal investigator for a randomized observer blinded controlled non inferiority trial to evaluate the safety and immunogenicity of locally manufactured inactivated bivalent whole cell-oral cholera vaccine (WC-OCV) 'Cholvax' in Bangladeshi healthy adults and children funded by the International Vaccine Institute and the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, specific and financially significant*.
- Serves as principal investigator on a trial to assess a cost-effective and impactful strategy for deploying oral cholera vaccine in children in urban slums in Bangladesh funded by Gavi, the Vaccine Alliance. This interest was assessed as non-personal, specific and financially significant*.

Noni MacDonald:

- Served as consultant in regard to vaccine-related issues (Facilitator Annual Retreat Report January, 2016; Facilitator Global Staff Retreat of the WHO Vaccine Preventable Diseases Programme Area Network March, 2016; Facilitator Meeting of the International Network of NITAGs May, 2016; Consultant WHO EURO Sub-regional technical consultation on vaccination opposition. June, 2016; Facilitator Vaccination in humanitarian emergency situations. October 2016; Consultant Ontario Ministry of Health and Longterm Care. January, 2017.) to WHO and WHO collaborating center. Each of these interests were assessed as personal, non-specific and financially insignificant*.
- Her institution[1] receives research from WHO to conduct a systematic review of global surveillance for adverse events following immunization during pregnancy. This interest was assessed as non-personal, non-specific and financially insignificant*.

[1] As per WHO assessment of conflicts of interests, "Institution" relates only to the expert's research/or work unit, as subdivision of the department

- Her institution[1] received research support from WHO to survey obstetricians/ gynecologists& midwives on their perception of product monographs and flu vaccines safety in pregnancy. This interest was assessed as non-personal, non-specific and financially significant*.
- Her institution[1] receives grants from the Canadian Institutes of Health Research to conduct studies on vaccine pain and hesitancy for which she serves as on co-investigator. This interest was assessed as non-personal, non-specific and financially significant*.

Terence Nolan:

- His institution[1] receives research support from 2016-2019 from Novavax to participate in a large multicenter RCT of an RSV-F experimental vaccine administered to pregnant women. Participated in an investigator initiation and training meeting for the trial. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** receives research support in 2015-19 to conduct a candidate 2-component Meningococcal B vaccine Phase 2 study in toddlers from Pfizer. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** received research support in 2015 from GSK/Novartis to conduct a study of Meningococcal B vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** receives research support in 2015-2017 to conduct a study in pregnant women and their offspring on dTap vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** received research support until 2014 to conduct an influenza cell-based vaccine clinical trial from Novartis. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** received research support in 2015-2016 to conduct a follow-up clinical trial on a birth dose of Pertussis Vaccination from GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution**Error! Bookmark not defined.** receives research support from 2013-2016 to conduct a Meningococcal ACWY vaccine clinical trial from GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as principal investigator for a clinical trial assessing the antibody response and persistence following MenACWY-TT funded by GSK and Murdoch Children's Research Institute. This interest was assessed as non-personal, non-specific and financially significant*.
- Served on a GSK Pertussis Scientific Advisory Board, Buenos Aires in April 2016 on pertussis vaccination and new vaccine development for use in pregnancy and for the elderly. This interest was assessed as non-personal, non-specific and financially significant*.
- Served on a GSK Pertussis Scientific Advisory Board, London in March 2014. This interest was assessed as non-personal, non-specific and financially significant*.
- Received a payment for contributing to pertussis education program development and speakers' bureau by MedScape funded by an untied educational grant from GSK in 2015 and 2016. This interest was assessed as personal, non-specific and financially significant*.
- Contributed to the Bionet Asia pertussis symposium in Bangkok in January 2017. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves as Chair of the Statens Serums Institute DSMB on adjuvanted low-dose IPV vaccine. This interest was assessed as personal, specific and financially insignificant*.
- His institution**Error! Bookmark not defined.** receives research support from Novavax from 2016-2019 to conduct a research study on RSV vaccine in pregnancy. This interest was assessed as non-personal, non-specific and financially significant*.

Kate O'Brien:

- Serves as technical expert consultant for Merck, ClearPath, Affinivax and PATH on pneumococcal vaccination. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves as technical expert consultant for Sanofi Pasteur on RSV. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Served as member of DSMB on malaria RTS,S vaccine funded by PATH-Malaria Vaccine Initiative. This ceased in 2014. This interest was assessed as non-personal, non-specific and financially significant*.
- Received funding for travel costs for a GSK Grand Convergence Meeting in 2015. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Her institution[1] currently receives research grants from GSK, Gavi, JSI Research & Training Institute, Inc., BMGF, Pfizer, regarding pneumococcal, rotavirus vaccines, biomarkers of

vaccination status, vaccine coverage, programmatic impact of multi-dose vaccines technical country support and decision making on pneumococcal/rotavirus vaccine, vaccine demand support, and/or pneumonia etiology. This interest was assessed as personal, non-specific and financially significant*.

- Her institution[1] receives research grants from the National Institutes of Health (NIH) regarding pneumococcal epidemiology and vaccines. This interest was assessed as personal, non-specific and financially significant*.
- Her institution[1] received research grants from Merck on adult vaccines until June 2016. This interest was assessed as non-personal, non-specific and financially significant*.
- Her institution[1] received research grants from BMGF regarding a disease surveillance, country support of pneumococcal and rotavirus vaccines, vaccine demand approaches, PCV policy optimization and pneumcooccal, Hib and meningococcus etiology work (disease burden estimates). This interest was assessed as personal, non-specific and financially significant*.
- Her institution[1] received research grants from Gavi regarding scientific communication support and PCV product assessment. This interest was assessed as personal, non-specific and financially significant*.
- Her institution[1] received research grants from the Pfizer Foundation regarding monitoring of routine immunization coverage in Pakistan. This interest was assessed as personal, non-specific and financially significant*.

Andrew Pollard:

- His institution[1] received research support until 2014 from GSK on Pneumococcal vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support until 2016 from Okairos on RSV vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support until 2015 from Pfizer on Meningococcal B vaccine, meningitis epidemiology and pneumococcal epidemiology. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support until 2014 from Novartis on Meningococcal B vaccine. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study an Ebola vaccine developed by Janssen (2015-current) funded by a European Commission IMI grant (EBOVAC). This interest was assessed as non-personal, specific and financially significant*.
- His institution[1] received research support on a grant for a study on the cause of fever with Bexsero funded by a European Commission grant (EUCLIDS; funding 2011-2017). The vaccine for the study is provided by Novartis/GSK. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study on the efficacy of a typhoid vaccine (Tybar-CV) produced by Bharat Biotech, India (2013-2016) funded by the Bill and Melinda Gates Foundation. No funding was received from Bharat Biotech, the grant was funded by the Bill and Melinda Gates Foundation. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study on the genes expressed in children when they receive an adjuvanted influenza vaccine (FluAd, Novartis) funded by a European Commission grant (ADITEC, 2011-2016). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study on the treatment of encephalitis in children with intravenous immunoglobulin (supply and distribution funding agreement with CSL Behring) funded by the National Institute for Health Research (2015-2020). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study on the infant pneumococcal vaccine schedule in Nepal (2013-2017), funded by Gavi, the Vaccine Alliance. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received unrestricted educational grants from Novartis/GSK/Astra Zeneca/Sanofi Pasteur MSD in 2014; Novartis/GSK/Astra Zeneca in 2015 and Pfizer/GSK/Astra Zeneca in 2016 for a course on infection and immunity in children. This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support until 2014 from SPMSD on a hexavalent infant vaccine. This interest was assessed as non-personal, non-specific and financially significant*.

- His institution[1] received research support on a grant for a study on pertussis vaccines funded by a European Commission grant (PERISCOPE, 2016-current). This interest was assessed as non-personal, non-specific and financially significant*.
- His institution[1] received research support on a grant for a study pneumococcal pneumonia and carriage by a European Commission Horizon 2020 grant (2016-2020). This interest was assessed as non-personal, non-specific and financially significant*.

Nikki Turner:

- Her institution[Error! Bookmark not defined.] received a research grant from GSK for a vaccine effectiveness trial of conjugate pneumococcal PCV10 vaccine. This interest was perceived as non-personal, non-specific and financially significant*.
- Her institution[Error! Bookmark not defined.] receives a research grant from GSK to assess the safety of pertussis vaccine during pregnancy. This interest was perceived as non-personal, non-specific and financially significant*.
- The Immunisation Advisory Centre, for which she serves as director, ran a one-day symposium - the NZ Influenza Symposium on the 12 November 2014, and they accepted sponsorship from Sanofi, GSK, Abbott and MSD. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as non-personal, non-specific and financially significant*.
- The Immunisation Advisory Centre, for which she serves as director, ran a national immunisation conference in September 2015 with sponsorship from GSK, Myland EPD, Sanofi, Pfizer, Pharmac, bioCSL, MSD, Bell Technology, Rollex Medical, Green Cross Health, Obtain and Temprecord. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as non-personal, non-specific and financially significant*.
- The Immunisation Advisory Centre, for which serves as director, organized a national influenza symposium in November 2016 with sponsorship from GSK, Myland EPD and Sequris towards the cost of running the symposium. None of the speakers were funded and the sponsorship had no involvement in the setting of the programme. This interest was assessed as non-personal, non-specific and financially insignificant*.

Fred Were:

- Serves on the safety monitoring committee for an evaluation of i.v. injection of vialled P falciparum sporozoites until 2018. The sporozoite product is developed by Sanaria. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves on the PATH advisory board for the whole cell pneumococcal vaccine from 2018. This interest was assessed as non-personal, non-specific and financially insignificant*.
- Serves as principal investigator for a trial on fractional dose use of PCV sponsored by the Bill & Mellinda Gates Foundation through the Wellcome Trust Kenya. This interest was assessed as non-personal, non-specific and financially significant*.
- Serves as member of a DSMB for fractional dose use of yellow fever vaccine in Kenya sponsored by Epicentre through MSF France. This interest was assessed as non-personal, non-specific and financially significant*.

Charles Wiysonge:

- Will serve as the principal investigator for the Supporting National Independent Immunization and Vaccine Advisory Committees (SIVAC) Initiative at the Agence de Medecine Preventive (AMP), likely from May to June 2017. This interest was assessed as personal, specific and financially significant*.

* According to WHO's Guidelines for Declaration of Interests (WHO expert), an interest is considered "personal" if it generates financial or non-financial gain to the expert, such as consulting income or a patent. "Specificity" states whether the declared interest is a subject matter of the meeting or work to be undertaken. An interest has "financial significance" if the honoraria, consultancy fee or other received funding, including those received by expert's organization, from any single vaccine manufacturer or other vaccine-related company exceeds 5,000 USD in a calendar year. Likewise, a shareholding in any one vaccine manufacturer or other vaccine-related company in excess of 1,000 USD would also constitute a "significant shareholding". Funding going to the SAGE member's research unit needs to be declared.

The above summary of reported interests was made available for public notice and comment on the WHO SAGE website prior to the April 2017 SAGE meeting. No comments have been received.