

# Meeting of Strategic Advisory Group of Experts on Immunization (SAGE), 20–22 October 2015

## DECLARATION OF INTERESTS

All 15 SAGE members (Jon Abramson, Yagob Al-Mazrou, Narendra Arora, Alejandro Cravioto, Juhani Eskola, Ilesh Jani, Jaleela Jawad, Kari Johansen, Terence Nolan, Kate O'Brien, Claire-Anne Siegrist, Piyanit Tharmaphornpilas, Nikki Turner, Fredrick Were and Charles Wiysonge) participating in the meeting updated their declaration of interest ahead of the meeting. Non-conflicted members of the Malaria Policy Advisory Committee (MPAC) (Fred Binka, Patricia Graves, Rose Leke, Sylvia Meek, Kamini Mendis, Allan Schapira, and Nicholas White) equally participated in the decision making for the joint session on the use of Malaria vaccine.

Seven SAGE members reported relevant interests, which were assessed not to constitute a conflict of interest and all members could fully participate in all sessions.

### **Jon Abramson:**

- His institution<sup>1</sup> received a research grant in 2013 from MedImmune to conduct a post-marketing case-control study of the effectiveness of the quadrivalent live attenuated influenza vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.

### **Juhani Eskola:**

- Received consultancy fees for membership in Novartis Data Safety Monitoring Board for typhoid vaccines. This interest was assessed as personal, non-specific and financially insignificant\*.
- Received consultancy fees for membership in Novartis Data Safety Monitoring Board for meningococcal vaccines. This interest was assessed as personal, non-specific and financially insignificant\*.
- His institution<sup>1</sup> has a large joint research programme with GlaxoSmithKline on pneumococcal vaccines. This interest was assessed as non-personal, non-specific and financially significant\*.

### **Terence Nolan:**

- His institution<sup>1</sup> receives research support as well as received a travel grant in 2015 to conduct a candidate 2-component Men B vaccine Phase 2 study in toddlers from Pfizer. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>1</sup> received research support in 2015 from GSK/Novartis to conduct a study of MenB vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>1</sup> receives research support as well as received a travel grant in 2015 to conduct a study on dTap vaccine. This interest was assessed as non-personal, non-specific and financially significant\*.
- His institution<sup>1</sup> receives research support 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<sup>1</sup> receives research support 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<sup>1</sup> receives research support 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 personal, non-specific and financially significant\*.
- Served on the GSK Pertussis Scientific Advisory Board, London in March 2014. This interest was assessed as non-personal, non-specific and financially insignificant\*.

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

**Kate O'Brien:**

- Serves as technical expert consultant for Merck on pneumococcal vaccination. 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, 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<sup>1</sup> currently receives research grants from GSK, BMGF, National Institutes on Health (NIH), and GAVI regarding pneumococcal, rotavirus vaccines, technical country support and decision making on pneumococcal/rotavirus vaccine, vaccine demand support, and/or pneumonia etiology. This interest was assessed as non-personal, non-specific and financially significant\*.

**Claire-Anne Siegrist:**

- Developed and owns the Viavac immunization management software destined to support Swiss health care professionals to follow the official immunization recommendations. This interest was assessed as personal, non-specific and financially significant\*.
- Owns a patent for the neonatal use of a DC-chol adjuvant. This interest was assessed as personal, non-specific and financially insignificant\*.
- Owns a patent for the use of Viaskin as an epicutaneous booster. This interest was assessed as personal, non-specific and financially insignificant\*.
- Her institution<sup>1</sup> receives a research grant from sanofi pasteur on the immunology of novel adjuvants. This interest was perceived as non-personal, non-specific and financially significant\*.
- Her institution<sup>1</sup> received a research grant in 2015 for a phase I clinical trial of the VSV-EBOV Ebola vaccine supported by the Wellcome Trust. This interest was perceived as non-personal, specific and financially significant\*.
- Her institution<sup>1</sup> will receive a research grant from DBV technologies for a Phase I proof-of-concept study of an epicutaneous pertussis booster with Viaskin. This interest was perceived as non-personal, non-specific and financially significant\*.

**Nikki Turner**

- Her institution<sup>1</sup> receives 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<sup>1</sup> 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\*.
- Her institution<sup>1</sup> received a research grant from GSK on best practice models in 2012/2013. This research is now funded by the NZ Health Research Council. This interest was perceived as non-personal, non-specific and financially significant\*.
- The Immunisation Advisory Centre, for which Nikki Turner is the 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 Nikki Turner is the Director, ran a national immunisation conference in September 2015 with sponsorship from GSK, Myland EPD, Sanofi, Pfizer, Pharmacia, 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\*.

**Fred Were:**

- Serves on the safety monitoring committee for an evaluation of i.v. injection of vialled *P falciparum* sporozoites. 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 2013. This interest was assessed as non-personal, non-specific and financially insignificant\*.

### **MPAC members**

Members of MPAC with potentially perceived conflicts of interest were excluded from the decision making process and are not listed in this summary. Of the 7 members who participated in the decision making, 5 of them reported relevant interests that are summarized below.

#### **Fred Binka:**

- Receives research support from the Bill & Melinda Gates Foundation (BMGF) for the InDepth Network Effectiveness and Safety Studies (INESS) related to the safety and effectiveness of malaria drugs. This interest was assessed as non-personal, non-specific and financially significant\*.

#### **Patricia Graves:**

- Receives consultancy fees from WHO and UCSF to review malaria and vector-borne disease programmes. This interest was assessed as personal, non-specific and financially significant\*.

#### **Rose Leke:**

- Receives funding from the National Institute of Allergy and Infectious Diseases (NIAID), USA for research on the impact of Intermittent Preventive Treatment in pregnancy on specific antibody levels. This interest was assessed as non-personal, non-specific and financially significant\*.
- Served on the Data Safety and Monitoring Board (DSMB) in 2013 for a Pfizer study on AZCQ during pregnancy. This interest was assessed as non-personal, non-specific and financially significant\*.

#### **Sylvia Meek:**

- Is technical director of the Malaria Consortium which receives research funding from the Bill & Melinda Gates Foundation, DfID, and CDC. This interest was assessed as being non-personal, non-specific, and financially significant\*.

#### **Nick White:**

- His institution<sup>1</sup> receives support from the Wellcome Trust and BMGF for research on Mass Drug Administration. This interest was assessed as non-personal, specific and financially significant\*.
- His institution<sup>1</sup> receives funding from Wellcome Trust, MMV, BMGF, UKAID, Novartis, GSK, Holley-Cotec and DNDi for research related to anti-malarial drugs. This interest was assessed as non-personal, non-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 stated conflicts were made available for public notice and comment 2 weeks prior to the SAGE meeting in order to provide information on interests or biases relating to potential conflicts of SAGE and MPAC members. No comments on any of the above stated interests were received ahead of the meeting.