Appendix I:

Strategic Advisory Group of Experts (SAGE) Working Group on rabies vaccines and rabies immunoglobulins (established July 2016)

Terms of Reference

The Working Group is requested to review the scientific evidence and relevant programmatic considerations, to formulate proposed recommendations on the use of rabies vaccines and immunoglobulins.

Specifically, the Working Group will be asked to review the following elements:

1. Assess evidence and country practices in the use of human rabies vaccine and rabies immunoglobulins (RIG), including that of targeted vaccination of high risk communities in rural settings;
2. Review the new evidence on the need for pre-exposure prophylaxis (PREP) booster doses and the cost-effectiveness of the interventions;
3. Assess the most recent evidence on the potential shortening of post-exposure prophylaxis (PEP) schedules and new regimens;
4. Review the evidence and revisit the current WHO position for RIG and monoclonal antibody use with the view to improve access to care and increase public health impact;
5. Assess the implementation and evidence of the current recommendation on intradermal use of cell culture-derived vaccines (CCV);
6. Economic burden of rabies and cost-effectiveness of vaccination as well as modelling data should be assessed to inform rabies vaccination strategies (including vaccination in the context of other control strategies);
7. Consideration should be given to new vaccines in different phases of clinical trials or in the process of obtaining WHO prequalification and/or national market authorization by mid/end 2016.

Composition

SAGE members
- Kate O’Brien, (Chair of Working Group), Johns Hopkins Bloomberg School of Public Health, USA.
- Terry Nolan, University of Melbourne, Australia.

Experts
- Ahmed Be-Nazir, National Institute of Preventive and Social Medicine, Dhaka, Bangladesh.
- Lucille Blumberg, National Institute for Communicable Diseases, Johannesburg, South Africa.
- Deborah Briggs, Kansas State University College of Veterinary Medicine, Manhattan, USA.
- Mathurin Cyrille Tejiokem, Centre Pasteur du Cameroun, Yaounde, Cameroon.
- Luzia Queiroz, University of Sao Paulo State, Sao Paulo, Brazil.
- Naseem Salahuddin, The Indus Hospital Karachi, Karachi, Pakistan.
- Gade Sampath, Institute of Preventative Medicine, Hyderabad, India.
- Arnaud Tarantola, Institut Pasteur du Cambodge, Phnom Penh, Cambodia.
- Mary Warrell, University of Oxford, Oxford, UK.
- Henry Wilde, Chulalongkorn University, Bangkok, Thailand.

WHO secretariat
- Bernadette Abela-Ridder (Focal point)

Declaration of interests

All members completed a declaration of interests form. Two SAGE members and two Working Group members reported relevant interests summarized below:
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, 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 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*.

Terence Nolan:
- His institution 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, specific and financially significant*.
- His institution 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 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 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 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 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*.

Arnaud Tarantola
- Serves as advisor to the Cambodian Ministry of Health on rabies epidemiology, research and prevention and assisted with development of a national strategy against rabies. This interest was assessed as personal, specific and financially insignificant*.

Mathurin Cyrille Tejokem
- His institution receives a grant from Sanofi Pasteur until 2016 to fund a pilot study on the establishment of a rabies surveillance system in Cameroun. This interest was assessed as personal, specific and financially significant*.