Advance Market Committee (AMC) Independent Assessment Committee (IAC)

Eligibility Determination Meeting

Public summary of meeting

17th October 2017 – Teleconference

Participants

IAC members:

- Arthur Elliot, Senior Programme Manager, Vaccines and Anti Viral Agents, US Department of Health and Human Services, USA
- Bernard Fanget, CEO, Bernard Fanget Consulting; VP R&D and Pharmaceutical Development, Neovacs
- Claire Broome, Adjunct Professor Division of Global Health Rollins, School of Public Health Emory University Atlanta, Georgia, USA (Chair)
- George Amofah, Lecturer, School of Public Health, University of Ghana, Legon
- Halvor Sommerfelt, Professor of Epidemiology, Center for International Health, University of Bergen, Norway; Director, Centre for Intervention Science in Maternal and Child Health
- Mary Kitambi, Public Health Specialist Ministry of Health, Community Development, Gender, Elderly and Children, Tanzania
- Soonman Kwon, Chief of Health Sector Group (Tech. Advisor), Asian Development Bank, Philippines; Professor & Former Dean, School of Public Health, Seoul National Univ., Korea

AMC Secretariat/Gavi:

- Veronica Denti, Sr. Programme Manager
- Helene Gaudin de Villaine, Associate Legal Counsel

WHO:

- Drew Meek, Scientist, HIS/EMP/PQT

Objective of meeting

As per the AMC Procedures Memorandum, the objective of the meeting was to review GSK's application for AMC eligibility for PCV10 4 dose vials and determine if the candidate vaccine met the Target Product Profile (TPP) for the AMC.

Commencement

The IAC met by conference call on 17th October 2017. Seven of nine members of the IAC attended the call and a minimum quorum was obtained as required in the IAC Charter and Bylaws. It was reconfirmed that no member had a conflict of interest in this meeting's decision. The meeting was chaired by Dr. Claire Broome, IAC Chairperson. The meeting started at 15:10 CEST.

Review of TPP criteria attributed to WHO prequalification

Dr. Andrew Meek reviewed the TPP criteria attributed to WHO prequalification[1] for the IAC. Prior to the meeting, the IAC received WHO's written report outlining how the candidate vaccine met the criteria, which are listed below.

Attribute	Minimally Acceptable Profile
A. Immunogenicity	Immunogenicity should be demonstrated in accordance with WHO criteria, which are based on non-inferiority to a licensed pneumococcal vaccine as outlined in WHO *Recommendations for the production and control of pneumococcal conjugate vaccines.* (WHO Technical Report Series, No 927, 2005 and any subsequent published guidance).
B. Safety, reactogenicity and contra-indications	The safety and reactogenicity profile should be comparable to, or better than that of the currently licensed pneumococcal conjugate vaccine. Contra-indications should be restricted to known hypersensitivity to any of the vaccine components.
C. Interference and co-administration with other vaccines	There should be no clinically significant interaction or interference in relation to safety and immunogenicity with concurrently administered vaccines.

[1] As per the AMC Procedures Memorandum, Schedule 2, Paragraph A.

D. Product presentation	The vaccine must be available in mono-dose or low multi-dose presentations. Mono-doses must be either a single dose vial or a auto-disable compact pre-filled device. Low multi-dose presentations must be formulated and labelled in compliance with WHO policy or guidance.
E. Storage and cold chain requirements	The product must be stable at 2-8 °C with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in *Making use of vaccine vial monitors. Flexible vaccine management for polio* (WHO/V&B/00.14).
F. Packaging and labelling	Name and labelling must be in accordance with WHO *Recommendations for the production and control of pneumococcal conjugate vaccines.* (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23).
G. Product registration and prequalification	The product must be WHO pre-qualified in accordance with *Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies* (WHO TRS 978, Annex 6).
H. Post marketing surveillance	Post-marketing surveillance should be conducted in accordance with national regulatory authorities and WHO prequalification requirements as set out in *Guideline for preparation of the product summary file for vaccine prequalification* (WHO/IVB/06.16) , *Guidelines on clinical evaluation of vaccines: regulatory expectations* (WHO Technical Report Series, No 924, 2004) and any relevant published guidance.

IAC discussion on the TPP criteria attributed to WHO prequalification

The IAC confirmed that they were comfortable with the conclusions from the WHO prequalification set forth in the WHO prequalification review. In answer to questions from the IAC, Dr Meek confirmed that:

- The stability of the 4 dose vial was comparable to that of the 2 dose vial for the duration of time monitored to date
- The preservative in the 4 dose vial of PCV10 is the same as in the 4 dose vial of PCV13
- Data on co-administration with IPV refers to the currently PQed and AMC-eligible 2 dose presentation, and there is no new IPV co-administration data specific to the 4 dose presentation
- GSK has confirmed that the presumed secondary packaging (carton) dimensions are correct

Review of TPP criteria assessed by the IAC

The IAC assessed the vaccine using the TPP IAC assessment criteria[2], set forth in the table below.

Attribute	Minimally Acceptable Profile
(a) **Vaccine serotypes**	The serotypes in the vaccine formulation must cover at least 60% of the invasive disease isolates in the target region, and must include serotypes 1, 5 and 14 which are the most frequent isolates in GAVI Eligible Countries
(b) **Target population/ target age groups**	The vaccine must be designed to prevent disease among children <5 years of age and in particular be effective in those <2 years of age.
(c) **Dosage schedule**	Vaccine scheduling must be compatible with national infant immunisation programmes and consist of not more than 3 doses in the first year of life. The first dose must be shown to be administrable at 6 weeks of life or earlier.
(d) **Route of administration**	Intramuscular or subcutaneous.
(e) **Product formulation**	Liquid formulation with a standard volume of 0.5 ml/dose.

[2] As per the AMC Procedures Memorandum, Schedule 2, Paragraph B.

IAC discussion on the TPP criteria assessed by the IAC

Dr. Claire Broome highlighted that due to the prior determination of AMC eligibility of the 2 dose vial and the non-inferiority of the 4 dose vial in relation to the 2 dose vial in terms of immunogenicity and serotype coverage, there was sufficient evidence for the 4 dose vial to meet the IAC assessment criteria as per the TPP.

Determination

The IAC members participating in the meeting unanimously determined that PCV10 4 dose vial vaccine presentation meets all of the TPP criteria and that the candidate vaccine is therefore eligible for purchase pursuant to the terms and conditions of the pneumococcal AMC.

The meeting was adjourned at 15.52 CEST.