

AMC Independent Assessment Committee (IAC)

Eligibility Determination Meeting

Summary of Meeting

23 August 2010

Teleconference

IAC Members Participants

- **Claire Broome**, Adjunct Professor Division of Global Health Rollins School of Public Health Emory University Atlanta, Georgia, USA
- **Ingrid Callies**, Adviser to the Vice-President for Medical Affairs, Institut Pasteur, France
- **Bernard Fanget**, CEO, Bernard Fanget Consulting; and VP R&D and Pharmaceutical Development, Neovacs
- **Arthur Elliot**, Senior Program Manager, Vaccines and Anti Viral Agents, US Department of Health and Human Services, USA
- **Mary Kitambi**, Public-Private Partnership Coordinator, Ministry of Health and Social Welfare, Tanzania
- **Soonman Kwon**, Professor of Health Economics, Seoul National University, Korea
- **Halvor Sommerfelt**, Professor of Epidemiology, Center for International Health, University of Bergen, and Senior Consultant, Division of Infectious Disease Control, Norwegian Institute of Public Health, Oslo, Norway
- **Shahnaaz Kassam Sharif**, Chief Medical Specialist, Senior Deputy Director Medical Services, Head of Preventive and Promotive Health Services, Ministry of Health, Kenya
- **Vitaly Zverev**, Director, I.I. Mechnikov Institute of Vaccine Sera under the RAMS, Russia

GAVI

- **Debbie Adams**, Managing Director, Legal and Governance
- **Anthony Brown**, Senior Legal Counsel
- **Johanna Fihman**, Senior Programme Assistant, AMC
- **Jon Pearman**, Head, AVI

WHO

- **Joachim Hombach**, Coordinator Implementation Research, Initiative for Vaccine Research (IVR)
- **Drew Meek**, Scientist, FCH/IVB/QSS

UNICEF Supply Division (Observer)

- **Ann Ottosen**, Contracts Manager

Purpose of Meeting

The purpose of the meeting was to review Pfizer's application for AMC eligibility for Prevenar 13 and determine if the candidate vaccine met the TPP for the AMC.

Commencement

The Independent Assessment Committee (IAC) met by a conference call on 23 August 2010. Nine of 11 members of the IAC attended the call and a minimum quorum was obtained as required in the IAC Charter and Bylaw. The meeting was chaired by Dr. Claire Broome, IAC Chairperson. The meeting started at 16:00 CEST.

Programme Update

Jon Pearman presented a brief update on the status of introduction of pneumococcal vaccines in GAVI Eligible countries.

Review of TPP Criteria attributed to WHO Prequalification

Pfizer applied for AMC Eligibility on 15 January 2010. The AMC-Eligible Vaccine Information Package, including the Product Summary File, was provided to the IAC in due course. Drew Meek reviewed the TPP Criteria attributed to WHO prequalification (see table below) for the IAC. The IAC received WHO's written report outlining how the candidate vaccine met the criteria listed below prior to the meeting.

At the teleconference, Drew Meek reviewed those TPP Criteria. The IAC posed various questions to the WHO's representatives regarding post marketing surveillance and non-inferiority criteria; and discussed each criterion listed below, in turn.

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 <i>Recommendations for the production and control of pneumococcal conjugate vaccines</i> . (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.
(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 an auto-disableable 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 2-8oC with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in <i>Making use of vaccine vial monitors. Flexible vaccine management for polio</i> (WHO/V&B/00.14).
(f) Packaging and labelling	Name and labelling must be in accordance with WHO <i>Recommendations for the production and control of pneumococcal conjugate vaccines</i> . (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in <i>Guidelines on the international packaging and shipping of vaccines</i> (WHO/IVB/05.23).
(g) Product registration and prequalification	The product must be WHO pre-qualified in accordance with <i>Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies</i> (WHO/IVB/05.19).
(h) Post marketing surveillance	Post-marketing surveillance should be conducted in accordance with national regulatory authorities and WHO prequalification requirements as set out in <i>Guideline for preparation of the product summary file for vaccine prequalification</i> (WHO/IVB/06.16), <i>Guidelines on clinical evaluation of vaccines: regulatory expectations</i> (WHO Technical Report Series, No 924, 2004) and any relevant published guidance.

Review of TPP Criteria assessed by the IAC

The IAC discussed each TPP criterion attributed to itself (see table below) as per Schedule 2 of the AMC Procedures Memorandum.

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.

Determination

The IAC members confirmed that they do not have any conflict of interest to disclose in application of the IAC's Charter and Bylaws. As there is no conflict of interest that would affect a determination decision about the candidate vaccine, all the IAC members participating in the meeting were able to vote and unanimously determined that Prevenar 13 vaccine meets all of the TPP criteria and that the candidate vaccine is therefore eligible for purchase pursuant to the terms and conditions of the AMC for Pneumococcal disease.

The meeting was adjourned at 17.30 CEST.

Recommendation

The IAC strongly encourages the conduct of post-introduction surveillance studies of particular relevance to GAVI eligible countries. These studies should address the following issues:

- Effectiveness of the 13-valent vaccine in GAVI Eligible Countries.
 - Impact on IPD in ages outside vaccine target age and on target age children who have not received the vaccine (herd protection);
 - Impact on non-specific outcomes such as radiographic pneumonia,
 - Effectiveness with field variability of EPI schedule, such as single dose at 6 weeks.
- Serotype specific effectiveness of PCV 13
The IAC noted the general interest in serotype specific effectiveness and particularly those serotypes not included in the 7-9-valent vaccines – such data may come from global studies, or may come from the Gambia, Kenya and South Africa studies.
- Cost effectiveness of pneumococcal conjugate vaccine introduction
- Information on duration of protection

WHO surveillance expertise and funding represent a real opportunity; however answering the questions listed above will require using a range of valid methodologies, and it would be appropriate to revisit whether the studies currently planned will address these questions, and whether sufficient funding is available.

The IAC also highlighted the need to have a coherent strategy for prevention and treatment of pneumonia, including consideration of how the introduction of PCV may interact with Integrated Management of Childhood Illness (IMCI).

Finally, the IAC expressed their interest in seeing GAVI's Monitoring and Evaluation plans around the introduction of pneumococcal vaccines in GAVI Eligible countries.