AMC Independent Assessment Committee (IAC)

Eligibility Determination Meeting

Summary of Meeting

16 April 2010

Teleconference

IAC Members Participants

- **Robin Biellik**, Retired Senior Programme Officer, Vaccine introduction, Consultant for WHO
- **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
- **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 *(partially attended)*
- **Soonman Kwon,** Professor of Health Economics, Seoul National University, Korea
- **Tracy Lieu**, Director, Centre for Child Health Care Studies, Harvard Medical School, USA
- **Halvor Sommerfelt**, Professor of Epidemiology, Center for International Health, University of Bergen, Norway
- **Vitaly Zverev,** Director, I.I. Mechnikov Institute of Vaccine Sera under the RAMS, Russia

GAVI

- **Tania Cernuschi**, Senior Manager, AMC
- **Johanna Fihman,** Senior Programme Assistant, AMC
- **Tim Nielander,** General Counsel
- **Jon Pearman**, Head, AVI

WHO

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

Purpose of Meeting

The purpose of the meeting was to review GSK's application for AMC eligibility for Synflorix 2 dose presentation vaccine and determine if the candidate vaccine met the Target Product Profile (TPP) for the AMC.

Commencement

The AMC Eligibility Determination Meeting was scheduled to take place in London, UK, on 16th April yet due to the volcanic eruption in Iceland, the Independent Assessment Committee (IAC) had to meet by a conference call instead of meeting in person. Nine of 11 members of the IAC attended the call and the quorum was met as required in the IAC Charter and Bylaw. The meeting was chaired by Dr. Claire Broome, IAC Chairperson. The meeting started at 9.30am GMT.

Programme Update

Tania Cernuschi presented an update on the pneumo AMC programme including the procurement process, GAVI's financial status and ongoing and planned monitoring and evaluation activities.

Discussion on the AMC Baseline Study

The IAC inquired about the methodology and results of the AMC Baseline Study and asked GAVI to send a draft report to the IAC when the report is available.

Review of TPP Criteria attributed to WHO Prequalification

GSK applied for AMC Eligibility on 9 March 2010. The AMC-Eligible Vaccine Information Package was provided to the IAC in due course. Prior to the meeting, the IAC received WHO's written report outlining how the candidate vaccine met the criteria attributed to WHO prequalification (see table below) as per Schedule 2 of the AMC Procedures Memorandum

At the teleconference, Drew Meek reviewed those TPP Criteria. The IAC posed various questions to the WHO's representatives regarding immunogenicity, 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 *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.
	There should be no clinically significant interaction or interference in relation to safety and immunogenicity with

(c) **Interference and co-administration with other vaccines**	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-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 2-8oC 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/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 *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.

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 that would affect a determination decision about the candidate vaccine. The IAC members participating in the meeting unanimously determined that GSK Synflorix 2 dose presentation 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 2.30pm GMT.

Issue for further attention:

The IAC had a thoughtful and extensive discussion of the importance of comprehensive post-vaccine introduction surveillance and observational epidemiological studies, both to measure the effectiveness of vaccine components and the full impact of PCV introduction.