

AMC Independent Assessment Committee (IAC) Meeting

Summary of Meeting

3 November 2008

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
- **Arthur Elliot**, Senior Programme Manager, Vaccines and Anti Viral Agents, US Department of Health and Human Services, USA
- **Mary Kitambi**, Programme Manager for Expanded Program on Immunization, Tanzania
- **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

GAVI

- **Tania Cernuschi**, AMC Manager
- **Tim Nielander**, General Counsel
- **Nina Schwalbe**, Director of Policy

Guests

- **Professor David Goldblatt**, Chair TPP, Professor of Vaccinology and Immunology, Institute of Child Health, University College London and Great Ormond Street Hospital for Children NHS Trust.
- **Joachim Hombach**, Coordinator Implementation Research, Initiative for Vaccine Research (IVR), WHO
- **Orin Levine**, Director PneumoADIP

Commencement

The Independent Assessment Committee (IAC) met by conference call on 3 November 2008. Six of 8 members of the IAC attended the call and a quorum was present as required in the IAC provisional Charter and Bylaw. The meeting was chaired by Dr. Claire Broome - appointed interim IAC Chair by GAVI's Executive Secretary, Julian Lob-Levyt, upon recommendation by the AMC Secretariat.

Purpose of meeting

The main purpose of the call was the review and deliberation about the Pneumo AMC Technical Product Profile (TPP).

Clarification on the TPP

Clarification questions were raised around the following issues:

- 1) Complementarity of WHO prequalification and IAC eligibility processes.

GAVI and WHO explained that the Pneumo AMC TPP criteria have been divided in two subsets:

- i) Criteria incorporated in the WHO prequalification process – against which candidate vaccines will be assessed during prequalification.

- ii) Criteria specific to the AMC - against which candidate vaccines will be assessed by the IAC subsequent to prequalification.

This distinction was made explicit so that the IAC would not undertake parallel review of criteria included in the pre-qualification process.

2) Post-marketing surveillance and its implications on AMC price as well as on the IAC's role.

It was clarified that this TPP criteria will be assessed by WHO and that WHO would follow up on this issue as it does for any other vaccine.

3) Non inferiority.

The IAC discussed how non-inferiority could be determined.

4) Packaging and labeling.

The IAC discussed packaging and labeling criteria.

5) Liquid formulation.

The IAC reviewed the potential benefits of this formulation:

- Liquid vaccines are preferable in the field because they do not require reconstitution and therefore, avoid a step by health workers that takes time and can lead to errors
- The lyophilization step increases the costs of vaccine manufacturing, and increases the storage space needed for the diluent.

6) Global Serotype Project version 2

The Global Serotype Project (GSP) version 2 was completed and made available by PneumoADIP to WHO on November 3rd. GSP version 2 was scheduled to supersede GSP version 1 as the “metric” to be used to assess whether a vaccine meets the AMC TPP eligibility criteria for serotype coverage. Any potential future updates to the GSP will be used for country information purposes and demand assessments only and those updates will not change the requirements for suppliers.

DECISION

Agreed that the determination of non-inferiority for a complex multi-antigen product such as pneumococcal conjugate is difficult and WHO will be required to exercise judgment in the pre-qualification decision

Agreed: WHO will share available information on application of the non-inferiority criteria during the pre-qualification phase.

Agreed WHO and IAC agreed that the updated GSP version 2 should supersede GSP version 1 as a metric for AMC eligibility. Before approving the TPP with GSP version 2 as the metric the IAC asked WHO to:

- i) Analyze in more detail GSP version 2, specifically to assess the impact of model assumptions
- ii) Look at revised language in the TPP supplementary documentation to reflect newly acquired information.

Agreed: the postponement of endorsement until TPP supplementary documentation is updated to reflect newly acquired information from GSP version 2. WHO will forward GSP version 2 to GAVI and all IAC members.

Agreed: PneumoADIP will arrange teleconference to brief the IAC interim Chair, Claire Broome and any other interested members on GSP version 2.

Agreed: A telephone meeting among the IAC members would be held to review the completed and updated TPP documentation and endorse the TPP.

Update on AMC progress.

The IAC was updated on the AMC terms as defined in the IWG report and the draft Charter and Bylaws were distributed to the IAC members prior to the call and members committed to providing written comments to GAVI.

Resignation.

The IAC was informed of Walter Orenstein's departure from the IAC due to his new position with the Bill and Melinda Gate Foundation, which makes him ineligible for IAC membership