Licensure Strategies for Pneumococcal Conjugate Vaccines

March 8, 2001

DRAFT questions to the committee:

1. **Would non-inferiority immune response trials comparing a new pneumococcal conjugate vaccine with Prevnar™ be sufficient for inferring efficacy against invasive disease for the new product? If so, what immunological parameter(s) should be used?**

2. **What criteria should be considered to evaluate serotypes not contained in Prevnar™?**

3. **For a new pneumococcal conjugate vaccine, can data demonstrating clinical efficacy against AOM (acute otitis media) also be used to infer efficacy against invasive pneumococcal disease?**

4. **An invasive disease efficacy study may be performed in a non U.S. population(s) with a new pneumococcal conjugate vaccine:**

   a. **If efficacy is demonstrated, would data derived from such a trial support licensure of the vaccine in the U.S.?**

   b. **If so, what are the immunologic criteria that should be used to establish comparability to Prevnar™ in U.S. bridging studies?**