

GlaxoSmithKline's Infanrix_{DTPa}-HepB-IPVTM

March 7, 2001

DRAFT Questions to the VRBPAC:

The questions below have been used to provide a framework for the briefing document. The finalized questions will be presented at the March meeting.

Question #1 (VOTE): The following questions pertain to efficacy:

- A) Are the available data adequate to support the efficacy of DTPa-HepB-IPV vaccine when given to infants in a primary series at 2, 4, and 6 months of age?
- B) If the data are not adequate to address efficacy, what additional information should be requested?

Question #2 (VOTE): The following questions pertain to safety:

- A) Are the available data adequate to demonstrate the safety of the DTPa-HepB-IPV combination vaccine when given to infants in a primary series at 2, 4, and 6 months of age? Please comment on the increased rates of fever.
- B) If the data are not adequate to demonstrate safety, what additional information should be requested?

Discussion Point #3:

Please discuss the data submitted in support of the concurrent administration of other routinely recommended childhood immunizations with the DTPa-HepB-IPV vaccine in infants, i.e., *Haemophilus influenzae* type b vaccine and 7-valent pneumococcal conjugate vaccine (Prevnar).

Discussion Point #4:

Please identify any issues that should be addressed in post-licensure studies. Please specifically include a discussion of the safety and immunogenicity of concurrent administration of other routinely recommended vaccines (e.g., Prevnar); safety and immunogenicity of 4th and 5th dose of Infanrix® DTPa following a primary series of DTPa-HepB-IPV; and safety of a primary series of DTPa-HepB-IPV following a birth dose of hepatitis B vaccine.