Pneumococcal Vaccines: Accelerated Development and Introduction Plan (PneumoADIP)

1. Introduction

- Pneumococcal disease is the leading cause of morbidity and mortality in children under five years of age in low- and middle-income countries (LMICs). During childhood pneumonia and meningitis are the leading causes of death in children.

- Pneumonia (Pneumococcal Vaccine Prevented Pneumonia Category II) is a major cause of death in children under five years of age. Infants are also vulnerable to pneumococcal disease.

- Pneumococcal disease is a major public health concern in all regions, with an estimated 1.6 million deaths in children under five years of age worldwide.

- The European Pharmacopoeia (EP) 5.1.3 criteria requires a 2.5 year's accelerated temperature stability for both antigen (all thirteen serotypes) and preservative effectiveness.

- The United States Pharmacopeia (USP) <51> criteria requires a 2.5 year's accelerated temperature stability for both antigen (all thirteen serotypes) and preservative effectiveness.

- WHO (Multi-inoculation) criteria requires a 2.5 year's accelerated temperature stability for both antigen (all thirteen serotypes) and preservative effectiveness.

- The data supports the use of 2-PE as an effective preservative in both Prevenar 13™ and Multi-PE formulations.

- Preservative effectiveness test criteria:
  - Challenge: Serotype 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13
  - Antigen concentration: 5mg 2PE
  - Dose: 0.5mL
  - Incubation: 2.5 years at 2-8°C
  - Preservative effectiveness: Meets preservative effectiveness criteria for developing world (WHO Markets).

- Identifying a suitable preservative is crucial for the successful development of a multi-dose formulation.

2. Methods and Materials

- Formulations:
  - Multi-dose formulations of Prevenar 13™ contain thimerosal (0.02% propylparaben, 0.25% methylparaben, and 0.5% phenol) as a preservative.

- Preservation:
  - Thimerosal is not an effective preservative compared to 2-PE for Prevenar 13™.

3. Results

- A preservative concentration of 5mg 2PE/mL is required to demonstrate the long-term stability (2.5 years) of Prevenar 13™.

4. Conclusions

- Formulations with 2-PE in a Prevenar 13™ formulation is stable for 2.5 years at 2-8°C.

- Formulations containing 2-PE are recommended for developing world markets.

- The data supports the use of 2-PE as an effective preservative in both Prevenar 13™ and Multi-PE formulations.

5. References

- American Society for Microbiology (ASM) 2018
- United States Pharmacopeia (USP), 2019
- European Pharmacopoeia (EP), 2019
- World Health Organization, 2003
- United States Pharmacopeia (USP), 2019
- European Pharmacopoeia (EP), 2019

- Formulations contain 2-PE, propylparaben, methylparaben, and phenol.

- A preservative concentration of 5mg 2PE/mL is required to demonstrate the long-term stability (2.5 years) of Prevenar 13™.

- Formulations with 2-PE in a Prevenar 13™ formulation is stable for 2.5 years at 2-8°C.

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