

## US FDA approves Pfizer's 20-valent Pneumococcal Conjugate Vaccine for children

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Offers the broadest serotype coverage of any paediatric pneumococcal conjugate vaccine, helping to protect against all 20 serotypes contained in the vaccine



American pharmaceutical firm Pfizer Inc. has announced that the US Food and Drug Administration (FDA) has approved PREVNAR 20 (20-valent Pneumococcal Conjugate Vaccine) for the prevention of invasive pneumococcal disease (IPD) caused by the 20 *Streptococcus pneumoniae* (pneumococcal) serotypes contained in the vaccine in infants and children six weeks through 17 years of age, and for the prevention of otitis media in infants six weeks through five years of age caused by the original seven serotypes contained in PREVNAR.

In the United States, there remains a considerable burden of disease attributed to serotypes not included in currently approved pneumococcal conjugate vaccines (PCVs).

PREVNAR 20 builds on Pfizer's approved PREVNAR 13 vaccine, and includes seven additional serotypes (8, 10A, 11A, 12F, 15B, 22F and 33F) shown to be associated with antibiotic resistance, heightened disease severity, invasive potential, and prevalence in pediatric pneumococcal cases.

Moreover, data show that the additional seven serotypes included in PREVNAR 20 are among some of the most common serotypes causing paediatric IPD in countries, like the US, with existing pneumococcal vaccination programs. A study found that the seven additional serotypes alone accounted for an estimated 37% of IPD in US children under five years of age. The FDA's decision is based on results from the Phase 2 and Phase 3 clinical trial programs for the pediatric indication for PREVNAR 20.