

## Summary of the Pneumococcal Conjugate Vaccine (PCV) Product Assessment April 2017

This summary is based on a review of technical and programmatic evidence that may help countries make PCV product choices. Two products are available: PCV-10 and PCV-13. This document does not provide any recommendation for product choice and has not yet undergone formal WHO guideline review, so is not a formal recommendation from WHO. [The full report can be found here.](#)

### PCV Context & Background

- Both PCV-10 and PCV-13 have demonstrated high effectiveness and impact against invasive pneumococcal disease, pneumonia and other outcomes in a range of settings.

### Vaccine Characteristics

- The vaccine formulation of PCV-13 includes three more serotypes (3, 6A, 19A) than PCV-10.
- Both PCV10 and PCV13 have accrued extensive post-introduction safety surveillance data and have excellent safety profiles.

### PCV Performance & Impact Considerations

- PCV-10 and PCV-13 have shown comparable disease impact following use in routine use settings.
- Both vaccines have shown high efficacy against overall vaccine serotype disease. The efficacy for individual vaccine serotypes varies quite widely, with most serotypes having high efficacy, but some demonstrating modest or limited efficacy.
- Available data indicating that PCV-10 provides cross protection against two of the additional serotypes (6A and 19A) found in PCV-13 has prompted regulatory agencies, such as the European Medicines Agency, to label PCV-10 for protection against these types. There is insufficient evidence available to evaluate the effect of PCV-10 on serotype 3; given that the serotype is not included in the vaccine, efficacy is presumed to be absent.
- PCV-13 was found to be efficacious against serotypes 6A and 19A; there is inconsistent evidence of PCV-13 on serotype 3.
- There is almost no data on PCV-10 and PCV-13 interchangeability or performance of mixed product regimens in individual children. The current WHO position paper indicates that immunization should be completed using the same product. If this is not possible, the other PCV product should be used to complete the regimen.

### Economic & Financial Considerations

- Studies reviewed concluded that PCV-10 and PCV-13 were more cost-effective compared with PCV-7 or no vaccine.
- Comparisons of economic model results for PCV-10 versus PCV-13 are difficult to make. They vary across studies and may be impacted by uncertainties on serotype replacement (i.e. the increase of non-vaccine type incidence of disease as vaccine-type disease is reduced following use of the vaccine), herd effects (i.e., reduced disease among unimmunized persons due to reduced transmission), cross-protection from vaccine-related serotypes, and protection against acute otitis media from non-typeable *Haemophilus influenzae* (related to the protein carrier in PCV-10).
- Gavi-supported countries take on a higher level of vaccine co-financing as they transition out of Gavi support, thus the cost of PCV-10 or PCV-13 in the post-Gavi period should be considered.

### Programmatic Considerations

- The dosing schedule and number of doses recommended are the same for each product.
- The current PCV-10 presentation—2-dose vials without preservative—is expected to be replaced by 4-dose vials with preservative in 2018. PCV-13 is currently available in both 1-dose and 4-dose vials with preservative.
- The cold chain volume per 4 dose vial of PCV-10 (2.4 cm<sup>3</sup>) is two thirds that of PCV-13 (3.6 cm<sup>3</sup>).
- Training is required for use of both products prior to introduction, and if a product switch is undertaken. If a product and/or presentation switch occurs, health workers must be retrained, particularly on the multi-dose vial policy regarding how long the product can be kept after opening, and to avoid missed opportunities or excess wastage.

### Supply Considerations

- According to UNICEF, supply availability for both PCV products is sufficient to meet demand. Both PCV suppliers (Pfizer and GSK) have increased production capacity to meet existing and newly approved Gavi-country demand.