PUBLIC ASSESSMENT SUMMARY REPORT – Prevenar 13 MDV

At the time of the initial prequalification of Prevenar 13 (August 2010), the preparation and publication of Vaccine Public Summary Assessment reports (VPSARs) had not been introduced. This report concerning Prevenar 13 multidose vial (MDV) presentation covers only information concerning the assessment of the new formulation.

What is Prevenar 13 MDV?

Prevenar 13 MDV is a vaccine with the following composition:

Components	Quantity/dose (0.5 mL)
Thirteen pneumococcal conjugates (saccharides conjugated to CRM_{197}) Types: 1,3,4,5,6A,7F,9V,14,18C,19A.19F, 23 6B	2.2 µg/dose 4.4 µg/dose
Aluminium Phosphate (adjuvant)	0.125 mg Al
2-Phenoxyethanol (preservative)	4.0 mg
Sodium Chloride (excipient)	4.25 mg
Succinic Acid (excipient)	0.295 mg
Polysorbate 80 (excipient)	0.1 mg
Water for Injection (excipient)	qs to 0.5 mL

Container

Prevenar 13 MDV is dispensed into 2 mL Type I borosilicate glass vials which are sealed with West 4432/50 gray, latex-free, chlorobutyl rubber stoppers and capped with aluminium flip-off seals.

Real time and accelerated stability reviewed supports the use of a VVM type 30. The VVM is incorporated into the label.

What is Prevenar 13 MDV used for?

Prevenar 13 MDV is indicated for:

- active immunization of infants, children, and adolescents from 6 weeks through 17 years of age against invasive disease, pneumonia and otitis media caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

- Active immunization of adults, aged 18 years and older, against pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

How is Prevenar 13 MDV used?

The clinical trial comparing the MDV and a single dose (SD) presentation used a primary immunization course in infants of three doses (administered at the same time as routine paediatric

vaccines). The product insert also indicates a two dose schedule, plus booster may be used (consistent with the SD PI). Schedules in older previously unvaccinated children, and adults are described in the PI.

The vaccine is administered intramuscularly. The preferred location for recipients two years or older is the deltoid muscle of upper arm. For children aged < two years, the anterolateral area of the thigh is recommended.

What are the vaccine characteristics?

Prevenar 13 MDV must be stored between 2-8°C. It must not be frozen. Under these recommended storage conditions, the vaccine is stable for 24 months from the date of manufacture.

The vaccine does contains 2-phenoxyethanol (4mg/dose) concentration as a preservative. Suitable preservative efficacy test data was provided to support the use of opened vials of this presentation in subsequent immunisation sessions in accordance with WHO Multidose vial policy http://www.who.int/immunization/documents/general/WHO_IVB_14.07/en/

Two secondary carton packaging types are available:

a carton of 25 vials (100 doses) Cold chain volume per dose is 3.6 cm^3.
b carton of 50 vials (200 doses) Cold chain volume per dose is 3.5 cm^3.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

The European Medicines Agency (EMA).

How has Prevenar 13 MDV been studied from the clinical point of view?

The EMA managed Prevenar 13 MDV as a variation to the existing marketing authorisation for Prevenar 13. In discussions between EMA and Pfizer, it was agreed that this variation should be supported by a clinical trial to evaluate immunogenicity and safety of the multidose presentation compared to the single dose presentation. The primary endpoint for each of the pneumococcal serotypes was the proportion of subjects achieving a serotype specific IgG concentration ≥0.35 µg/mL one month after the infant series for each vaccine group. The non-inferiority criterion was met for all 13 serotypes in the MDV group compared with the SD group one month after Dose 3 of the infant series. There were no differences in reactogenicity, local or systemic adverse reactions, or SAEs between the two presentations. No new safety issue was detected in this study.

Other information about evaluation of Prevenar 13 MDV:

In accordance with the EMA process, PQT considered the submission of the Prevenar 13 MDV presentation as a variation. The NRA of record for PQ of this product is EMA. Vaccines under the regulatory oversight of that agency are eligible for use of the Expedited Evaluation procedure. (see http://www.who.int/entity/immunization_standards/vaccine_quality/TRS_978_61st_report_Annex_6_PQ_vaccine_procedure.pdf?ua=1 and http://www.who.int/entity/immunization_standards/vaccine_quality/variations_pq_vaccine/en/index.html). Under that procedure, evaluation is based primarily on review of the NRA evaluation reports, which were provided with the application. Additional review of preservative efficacy (with respect to use under the multidose vial policy) and stability data (with respect to VVM assignment) and UN specific labelling data was conducted.

Testing of samples of the Prevenar 13 MDV was not required as part of the variation evaluation procedure. In the future, samples will be selected for testing as part of the annual targeted testing program of batches supplied through UN agencies.

This summary was last updated and published on 19 August 2016.