Unit: Technical Assessment Unit

Public assessment report for biological products

Prevenar 20

Administrative information:

Trade name of the medicinal product:	Prevenar 20
INN (or common name) of the active substance(s):	Pneumococcal Polysaccharide Serotype (1,3,4,5,6A,7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F) 2.2 ug ; Pneumococcal Polysaccharide Serotype (6B) 4.4 ug
Manufacturer of the finished product	Pfizer Ireland Pharmaceuticals, Grange Castle Business Park,Clondalkin,Dublin 22 - IRELAND
Marketing Authorization holder	Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgium - BELGIUM
Applied Indication(s):	1-Active immunization for the prevention of invasive disease, pneumonia, and acute otitis media caused by Streptococcus pneumoniae in infants, children, and adolescents from 6 weeks to less than 18 years of age. 2-Active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.

Pharmaceutical form(s) and strength(s):	Suspension for injection 0.5mL single-dose prefilled syringe
Route of administration	I.M injection
Type of registration (EMA/FDA – Local)	EMA approved

List of abbreviations

I.M	Intramuscular
20vPnC	20-valent Pneumococcal Conjugate Vaccine
DP	Drug Product
DS	Drug substance
MBC	Monovalent bulk Conjugate
OPA	opsonophagocytic activity

Dossier initial submission and evaluation process:

-The file evaluated according to EDA regulation based on reliance pathway (Reliance level I), the company submitted the following:

-Complete CTD file.

-EMA unreducted Assessement

1. **General introduction about the product including brief description of the AI, its mode of action and indications**

The 20-valent Pneumococcal Conjugate Vaccine (20vPnC) is a sterile, preservative-free intramuscular injection that protects against 20 Streptococcus pneumoniae serotypes. Each 0.5 mL dose contains 2.2 µg of each serotype antigen (except 6B, which has 4.4 µg), all conjugated to CRM197. It is formulated in a succinate buffer with NaCl, polysorbate 80, and aluminum phosphate as an adjuvant. The vaccine is supplied in a single-dose 1 mL glass syringe with a Luer lock.

2. **Quality aspects:**

- **Manufacturer**
- **Drug Substance**

Manufacture of drug substance is Pfizer Ireland Pharmaceuticals, Grange Castle Business Park,Clondalkin,Dublin 22 - IRELAND and Wyeth Pharmaceutical Division of Wyeth Holdings LLC. 4300 Oak Park Sanford, NC 27330 United States .

- **Drug Product:**

Manufacturer of the Drug Product is Pfizer Ireland Pharmaceuticals, Grange Castle Business Park,Clondalkin,Dublin 22 – IRELAND.

- **Stability**

Drug substance :

- Required Shelf Life:

Monovalent Bulk Conjugate	**Shelf Life**
Serotype 1	24 Months
Serotype 3	12 Months
Serotype 4	24 Months
Serotype 5	24 Months
Serotype 6A	24 Months
Serotype 6B	18 Months
Serotype 7F	24 Months
Serotype 8	48 Months
Serotype 9V	24 Months
Serotype 10A	48 Months
Serotype 11A	48 Months
Serotype 12F	48 Months
Serotype 14	24 Months
Serotype 15B	48 Months
Serotype 18C	24 Months
Serotype 19A	18 Months
Serotype 19F	24 Months
Serotype 22F	48 Months
Serotype 23F	24 Months
Serotype 33F	48 Months
CY CRM197 (Liquid)	48 Months
CY CRM197 (Lyophilized)	24 Months
DM CRM197 (Liquid)	48 Months
DM CRM197 (Lyophilized)	24 Months

Intermediate:

1-Pneumococcal Polysaccharide Intermediate	
Pneumococcal Polysaccharide Intermediate	Shelf Life
Serotype 1	48 Months
Serotype 3	24 Months

Serotype 4	48 Months
Serotype 5	48 Months
Serotype 6A	48 Months
Serotype 6B	48 Months
Serotype 7F	48 Months
Serotype 8	48 Months
Serotype 9V	48 Months
Serotype 10A	48 Months
Serotype 11A	48 Months
Serotype 12F	48 Months
Serotype 14	48 Months
Serotype 15B	48 Months
Serotype 18C	48 Months
Serotype 19A	48 Months
Serotype 19F	48 Months
Serotype 22F	48 Months
Serotype 23F	48 Months
Serotype 33	48 Months

2-Activated Saccharide Intermediate

Serotype 1	18 Months
Serotype 3	12 Months
Serotype 4	18 Months
Serotype 5	18 Months
Serotype 6A	18 Months
Serotype 6B	18 Months
Serotype 7F	18 Months
Serotype 9V	18 Months
Serotype 14	18 Months
Serotype 18C	18 Months
Serotype 19A	18 Months
Serotype 19F	18 Months
Serotype 23F	18 Months

-Suggested Storage Conditions:

-Monovalent bulk Conjugate (MBC): Store at 2-8 °C

-CRM 197 (CY& DM):

Frozen: store at -75±5 °C.

Lyophilized: store at -20±5 °C.

Intermediate:

Pneumococcal Polysaccharide Intermediate: store at -15 to -25 °C

Activated Saccharide Intermediate: store at -15 to -25 °C

Drug Product:

Required Shelf Life: 24 months

Suggested Storage Conditions: Store in refrigerator 2-8 °C

3.Non –Clinical aspect & Clinical aspect:

-The results of the in vitro similarity assessment demonstrated the immunogenicity of the seven new serotypes (8, 10A, 11A, 12F, 15B, 22F, and 33F) included in the 20vPnC vaccine. In vitro studies showed strong, dose-dependent OPA responses to monovalent conjugates. The combined conjugates also induced robust IgG and OPA responses. In rabbits, 20vPnC at the human clinical dose elicited strong, serotype-specific antibody responses with functional bacterial killing in OPA. These findings, along with toxicology and similarity data, support the use of Prevenar 20.

-In conclusion the overall benefit/risk of Prevenar 20 is favorable in Active immunization for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older. See sections 4.4 and 5.1 for information on protection against specific pneumococcal serotypes. Prevenar 20 should be used in accordance with official recommendations.

4.General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/product-information/prevenar-20-epar-product-information_en.pdf