

## VI.2 ELEMENTS FOR A PUBLIC SUMMARY

### VI.2.1 Overview of Disease Epidemiology

Pneumococcal infection is a leading cause of death throughout the world and is a major cause of infections of the lungs (especially pneumonia), swelling of the coverings on the brain and spinal cord (meningitis), middle ear infections (otitis media), and a severe infection in the blood (bacteremia or septicemia).

Pneumococcal infections occur throughout the world and can occur in anyone at any age, but are most likely in:

- Elderly people.
- People who have lost their spleen or whose spleen is not working.
- People who have low resistance to infections due to longstanding illnesses or infections (such as heart disease, lung disease, diabetes mellitus, kidney disease, liver disease or HIV infection).
- People who have low resistance to infections due to treatment that they have had for some illnesses (such as cancer).

### VI.2.2 Summary of Treatment Benefits

Pneumococcal polysaccharide vaccine is a pneumococcal vaccine. Vaccines are used to protect you or your child against infectious diseases. Your doctor has recommended that you or your child (two years of age and older) have the vaccine to help protect against severe infections caused by bacteria that are called pneumococci.

Pneumococci can cause infections of the lungs (especially pneumonia) and of the coverings over the brain and spinal cord (meningitis) and in the blood (bacteraemia or septicemia). The vaccine will only be able to protect you or your child against pneumococcal infections that are due to the types of these bacteria that are included in the vaccine. However, the 23 pneumococcal types in the vaccine include those that cause almost all (about nine out of ten) infections caused by pneumococci.

When the vaccine is given to you or your child, the body's natural defences make antibodies that help to protect against pneumococcal infections. **Error! No document variable supplied.**

### VI.2.3 Unknowns Relating to Treatment Benefits

PPV23 has not been studied in persons who are pregnant or breastfeeding.

## VI.2.4 Summary of Safety Concerns

### Important Identified Risks

**Table 35 Summary of Important Identified Risks**

| Risk   | What is Known  | Preventability  |
|--|--|---|
| Hypersensitivity reactions<br>Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. | As with any drug or vaccine, severe allergic reactions may very rarely happen following the use of this vaccine. Allergic reactions may be serious and require immediate treatment.<br>When these signs or symptoms occur, they usually develop very quickly after the injection is given and while you or your child is still in the clinic or doctor's practice. | Anyone who is allergic to any of its components should not receive pneumococcal polysaccharide vaccine. |

### Important Potential Risks

**Table 36 Summary of Important Potential Risks**

| Risk                    | What is Known   |
|-------------------------|---|
| Febrile convulsions     | Febrile seizures are convulsions triggered by a fever. Most febrile seizures last a minute or two, although some can be as brief as a few seconds while others last for more than 15 minutes. Most febrile seizures occur during the first day of a child's fever. Although they can be frightening to parents, the vast majority of febrile seizures are brief and harmless.<br>Febrile seizures do not cause brain damage or learning problems later in life. They also do not cause epilepsy or seizure disorder.            |
| Guillain-Barré syndrome | Guillain-Barré Syndrome (GBS) is a disorder in which a person's own immune system attacks the protective sheath of nerves throughout the body causing muscle weakness or even paralysis. The cause of GBS is unknown but it often occurs following recent viral infections and has been described following immunizations. GBS may be life-threatening. Most individuals, however, have good recovery from even the most severe cases of Guillain-Barré syndrome, although some may keep a certain degree of residual weakness. |

### Missing Information

**Table 37 Summary of Missing Information**

| Missing Information   | What is Known   |
|---|---|
| Exposure during pregnancy   | If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby or to breast-feed, ask your doctor or pharmacist for advice before taking this vaccine. |
| Exposure during lactation   | If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby or to breast-feed, ask your doctor or pharmacist for advice before taking this vaccine. |
| Effects of immunogenicity of live attenuated vaccines (other than ZOSTAVAX™) when concomitantly administered with Pneumovax | No information is available.  |



## **VI.2.5 Summary of Risk Minimization Measures by Safety Concern**

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the Package Leaflet (PL). The measures in these documents are known as routine risk minimization measures.

The Summary of Product Characteristics and the Package Leaflet for pneumococcal polysaccharide vaccine can be found in the product's EPAR page.

This medicine has no additional risk minimization measures.

## **VI.2.6 Planned Post-authorization Development Plan**

### **VI.2.6.1 List of Studies in Post-authorization Development Plan**

There are no studies in the post-authorization development plan for this medicine.

### **VI.2.6.2 Studies Which are a Condition of the Marketing Authorization**

There are no studies in the post-authorization development plan for this medicine.

## **VI.2.7 Summary of Changes to the Risk Management Plan Over Time**

This is the initial version of the Risk Management Plan for Pneumococcal polysaccharide vaccine.