

World Health Organization Grants Expansion To The Prequalification For Prevenar 13 To Include Adults 50 Years Of Age And Older

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Designation Allows for Broader Global Access to Vaccine for the Prevention of Pneumococcal Disease in Adults

"With the WHO prequalification, we are proud to be working with a leader in public health to help bring us one step closer to making this important vaccine accessible to all adults 50 years of age and older around the world."

[\(BUSINESS WIRE\)](#)--Pfizer Inc. (NYSE: PFE) announced today that the World Health Organization (WHO) has granted an expansion to the prequalification of Pfizer's pneumococcal conjugate vaccine, Prevenar 13¹ (Pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]), to include adults 50 years of age and older against pneumonia and invasive disease caused by the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) contained in the vaccine.

Prevenar 13 was previously prequalified for active immunization of infants and children from six weeks through 5 years of age against invasive pneumococcal disease, pneumonia and otitis media in August 2010.

"Prevenar 13 is the first and only pneumococcal vaccine to be granted WHO prequalification in the adult population," says Luis Jodar, vice president, Vaccines, Global, Medicines Development Group and Scientific Affairs, Pfizer. "This expanded designation will allow for broader global access to the vaccine and provide the opportunity for a new prevention option for adults 50 years of age and older in developing nations."

The WHO prequalification program aims to make quality, priority medicines available for the benefit of those in need. Consequently, this prequalification allows for the procurement of Prevenar 13 for adults 50 years of age and older, in addition to Prevenar 13 for children under 5 years of age, by United Nations agencies, and is for global use of the vaccine in a single-dose vial. The WHO prequalification process applies unified standards to vaccines and other medicinal products.

"We are committed to developing vaccines that can help people remain healthy through every stage of life," says Susan Silbermann, president and general manager, Vaccines, Pfizer. "With the WHO prequalification, we are proud to be working with a leader in public health to help bring us one step closer to making this important vaccine accessible to all adults 50 years of age and older around the world."

"Pfizer is committed to ensuring adult vaccination is prioritized as a key preventive tool around the globe – thereby helping protect this population from infectious diseases as they age," continued Silbermann.

Currently, Prevenar 13, or Pevnar 13 as it is called in the United States, Canada and Taiwan, is approved in adults 50 years of age and older in more than 70 countries, including Australia, Canada, the European Union, India, Mexico, Russia, Singapore, Turkey and the United States.

WHO Prequalification Expands Access

Now that Prevenar 13 has received WHO prequalification for its adult 50 years of age and older indication, Pfizer will work with global partners in the international community to help make the vaccine available to these adults, as well as infants and children, at risk of pneumococcal disease globally. As an expression of this commitment, Pfizer is pleased to participate in the Advance Market Commitment (AMC) program, which helps to ensure infants and young children in the world's poorest countries have access to pneumococcal conjugate vaccines.

To meet the growing global demand for Prevenar 13, Pfizer is increasing its manufacturing capabilities to help ensure product supply through a combination of capital investment, process improvements and efficiency measures throughout the supply network. Pfizer is also investing in the development of a preserved, multi-dose vial which, subject to WHO prequalification, is expected to offer an alternative option for developing countries. This additional investment further underscores the company's commitment to the prevention of pneumococcal disease through vaccination around the world, including in least developed countries.

To date, Pfizer has agreed to supply a total of up to 480 million doses of Prevenar 13 through 2023 to infants and young children in the poorest countries of the world under the AMC for pneumococcal vaccination.

Prevenar 13 for pediatric use is available in 16 of the 18 countries that have launched national immunization programs with a pneumococcal conjugate vaccine through the AMC.

The First and Only Conjugate Vaccine

Pevnar 13/Prevenar 13 is the only pneumococcal conjugate vaccine approved for use in adults 50 years of age and older. The vaccine uses company-pioneered conjugate technology that links the pneumococcal antigens to a carrier protein CRM₁₉₇, which has more than 20 years of clinical and commercial use in vaccines.

About Pneumococcal Disease

Pneumococcal disease is caused by the bacterium *Streptococcus pneumoniae*, also known as pneumococcus, which can infect people of all ages, although young children, older adults and individuals with certain chronic medical conditions are at heightened risk. Invasive pneumococcal disease occurs when bacteria invade parts of the body that are normally free from bacteria, such as blood or spinal fluid.

Pneumococcal disease is a leading global public health problem associated with high mortality and morbidity. It can be difficult to diagnose, as antibiotic-resistant strains can complicate treatment decisions, cause treatment failures, as well as increase the duration and cost of care.

Symptoms of pneumococcal disease vary depending on the particular type of clinical illness and its severity. For example, symptoms of pneumococcal pneumonia can include fever, shaking chills, cough and shortness of breath, while symptoms of pneumococcal meningitis can include fever, headache and neck stiffness.

Indications for Pevnar 13/Prevenar 13

In the United States, Pevnar 13 is indicated in adults 50 years of age and older for active immunization for the prevention of pneumonia and invasive disease caused by the 13 *Streptococcus pneumoniae* serotypes contained

in the vaccine (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). The vaccine is also indicated for use in children six weeks through 5 years of age for the prevention of invasive disease (e.g., meningitis, bacteremia) caused by 13 *Streptococcus pneumoniae* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F).

In the European Union, Prevnar 13 is indicated for active immunisation for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* in adults aged 50 years of age and older caused by 13 *Streptococcus pneumoniae* serotypes. The vaccine is also indicated for active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from six weeks to 5 years of age.

Important Safety Information for Prevnar 13

- Prevnar 13 should not be given to anyone with a history of severe allergic reaction to any component of Prevnar 13 or any diphtheria toxoid-containing vaccine
- Children and adults with weakened immune systems (e.g., HIV infection, leukemia) may have a reduced immune response
- In adults, the common side effects were pain, redness, or swelling at the injection site; limitation of arm movement; fatigue; headache; muscle pain; joint pain; decreased appetite; chills; or rash
- In adults, immune responses to Prevnar 13 were reduced when given with injected seasonal flu vaccine
- A temporary pause of breathing following vaccination has been observed in some infants born prematurely
- The most commonly reported serious adverse events in children were bronchiolitis (an infection of the lungs) (0.9%), gastroenteritis (inflammation of the stomach and small intestine) (0.9%), and pneumonia (0.9%)
- In infants and toddlers, the most common side effects were tenderness, redness or swelling at the injection site, irritability, decreased appetite, decreased or increased sleep, and fever

For the full prescribing information for Prevnar 13 in the U.S., please click here <http://www.pfizer.com/products/#prevnar13>

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