US FDA approves use of Sanofi's meningococcal vaccine in infants

Meningococcal infections, caused by the Neisseria meningitidis bacteria, can cause serious, sometimes deadly, bloodstream infections, as well as severe swelling in the brain and spinal cord.

Bengaluru: French drugmaker Sanofi said the U.S. Food and Drug Administration has approved its meningococcal vaccine for use in infants as young as six weeks, making it the first shot intended for the age group.

The vaccine, branded as MenQuadfi, is already approved for individuals aged two years and older to protect against the four most common strains of meningococcal bacteria - A, C, W and Y, the company said on Friday.

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British drugmaker GSK's shot Menveo is approved in children as young as two months and adults up to 55 years of age.

"I think for convenience factor and accessibility... it is nice to have options," said Dr. Patty Sabey, a pediatrician with Stanford Medicine Children's Health, ahead of the decision.

The approval was based on data from three late-stage studies involving more than 6,000 participants aged six weeks to 19 months, which showed that MenQuadfi was as effective as Menveo when co-administered with other routine pediatric vaccines.

Sabey said meningococcal vaccine is not a routine vaccine for infants in the U.S. even though young infants, especially under one year, are at higher risk of infection.

The U.S. Centers for Disease Control and Prevention currently recommends all adolescents aged 11 to 12 years should receive a meningococcal vaccine, followed by a booster dose at age 16 years.

The agency also recommends that individuals aged two months and older who are at increased risk of the disease should receive the vaccine.

According to preliminary data from the CDC, 503 confirmed and probable cases of meningococcal disease were reported last year, the highest since 2013.

(Reporting by Siddhi Mahatole and Mariam Sunny in Bengaluru; Editing by Sriraj Kalluvila and Leroy Leo)

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