BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Novartis infant meningococcal vaccine gets FDA nod

August 2, 2013 | Regulatory | By BioSpectrum Bureau



Singapore:Ã?Â The US FDA has approved Novartis' Menveo (Meningococcal Group A, C, W-135 and Y conjugate vaccine) for the prevention of meningococcal disease caused by four strains of the bacterium Neisseria meningitidis (N. meningitidis) in infants and toddlers from two months of age.

With this expanded indication, pediatricians in the US can now offer a single vaccine for the protection of infants, children and adolescents against four of the five most common serogroups that cause meningococcal disease.

Infants younger than seven months old are the most vulnerable age group to meningococcal disease in the US. In their first year of life, infants are more than seven times more likely to contract the disease than 14 to 24 year olds. Of the infants who contract the disease, more than 10 percent will die from it and of those who do survive, approximately one in every five will suffer permanent, devastating side effects, including amputations, hearing loss, paralysis and brain damage.

"Despite recommendations for routine immunization of adolescents, college students living in dormitories and certain infants in the US, meningococcal disease continues to kill and maim," said Mr Andrin Oswald, Head of Novartis Vaccines and Diagnostics.

"With this approval for the expanded use of Menveo, we hope that health authorities will deploy this vaccine to further reduce the burden of this devastating disease in the US," he added.

This FDA approval was based on data from three randomized multicenter studies involving more than 8,700 infants, conducted in Australia, Canada, Latin America, Taiwan and the US. The studies demonstrated that Menveo generated a robust protective immune response and was generally well tolerated when administered with other routine pediatric vaccines.