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FDA nod for Sanofi's Quadracel vaccine

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Sanofi Pasteur has announced that the US Food and Drug Administration (US FDA) has approved the use of Quadracel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Absorbed and Inactivated Poliovirus; DTaP-IPV) vaccine for active immunization against diphtheria, tetanus, pertussis and poliomyelitis in children four through six years of age.

"The FDA approval of Quadracel vaccine provides health care providers with a new combination vaccine, potentially reducing the number of vaccine injections children aged four through six would need. Our goal is to help remove barriers to timely immunization and we think this combination vaccine could help ensure children are getting vaccinated in line with current recommendations," said Dr David P Greenberg, vice-president, US Scientific and Medical Affairs, Sanofi Pasteur.

This FDA approval is based on the data from a pivotal multicenter, randomized, controlled, Phase III study designed to compare the safety and immunogenicity of Quadracel vaccine (DTaP-IPV) with DAPTACEL (DTaP) and IPOL (IPV) vaccines. This is in children four through six years of age who were previously vaccinated with DAPTACEL and/or Pentacel (DTaP-IPV/Hib) vaccines. Results show Quadracel vaccine has similar safety and immunogenicity profiles as compared to those of separately administered DAPTACEL and IPOL vaccines.