

GSK announces approval of Shingrix in China

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GlaxoSmithKline has announced that the National Medical Products Administration (NMPA) has approved Shingrix for the prevention of shingles (herpes zoster) in adults aged 50 years or older. Shingrix is a recombinant subunit adjuvanted vaccine given intramuscularly in two doses.

The approval is in response to last year's inclusion of Shingrix on a list of 48 'clinically urgently needed new medicines' in China designated for expedited review, reflecting the country's prioritization of critical new prevention and treatment options.

Shingles is caused by reactivation of the varicella zoster virus, the same virus that causes chickenpox. Nearly all adults over 50 have the shingles virus dormant in their nervous system, waiting to reactivate with advancing age.

Shingles affects nearly three million adults in China annually.

Dr. Thomas Breuer, Senior Vice President and Chief Medical Officer of GSK Vaccines said, "Today's approval of Shingrix in China is recognition of the significant scientific advance this vaccine represents. In the pivotal studies the vaccine has shown over 90% efficacy across all age groups in the prevention of shingles, a disease that affects one in three people across the Asia-Pacific region. It can result in lasting pain and other complications which can severely impact the quality of people's lives."

"We welcome the Chinese government's progress to enable faster entry of new products into China and we look forward to working with the relevant agencies to bring the benefits of this vaccine to local communities," he said.

Introduction of the vaccine into China will be phased, starting in 2020, to ensure consistent and reliable supply of the vaccine to all countries in which the vaccine has been launched. Over the next several years, GSK expects to increase supply of Shingrix globally and is investing in significant capacity expansion.

Shingrix is currently licensed for use in the EU, US, Canada, Japan and Australia.