

GSK Australia announces regulatory approval of respiratory syncytial virus vaccine AREXVY

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AREXVY has been approved by the Therapeutic Goods Administration (TGA) for Australians 60 and over



GSK Australia has received Therapeutic Goods Administration (TGA) approval of AREXVY (respiratory syncytial virus vaccine, adjuvanted) to protect against lower airway disease caused by RSV in adults aged 60 years and over. AREXVY is the first RSV vaccine to be approved for use in Australia.

RSV is a common and contagious respiratory virus that can cause cold- and flu-like symptoms in adults. RSV is often considered as an illness that mainly affects children, however RSV can also cause serious illness and in rare cases, even death, in older adults.

AREXVY, which has already been approved for use in the UK, the European Union, US, Canada and Japan, is a protein-based vaccine given as a single dose.

RSV is predominantly spread by inhaling airborne droplets from those with the infection, or through contact with contaminated surfaces, and is therefore capable of spreading rapidly within households. RSV infections typically peak during autumn and winter in temperate climates in Australia, alongside other respiratory viruses, however, RSV can be caught at any point throughout the year.

The TGA registration of AREXVY is based on the results of GSK's international phase III clinical trial, which compared AREXVY with placebo in almost 25,000 people aged 60 years or older: