

Hong Kong approves Pfizer's vaccine to fight against lower respiratory tract disease

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The first and only bivalent, single-dose vaccine that fights against both RSV A and RSV B disease



American firm Pfizer Inc. has announced that the Hong Kong Department of Health (DH) has granted marketing authorisation for the company's bivalent Respiratory Syncytial Virus (RSV) prefusion F (RSVpreF) vaccine to fight against lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in individuals aged 60 years and older, and infants from birth up to six months of age through the active immunization of pregnant individuals.

Pfizer is currently the only company with an RSV vaccine suitable for use in both older adults and pregnant individuals. RSV is a contagious virus and a common cause of respiratory illness worldwide. The virus can affect the lungs and breathing passages of an infected individual, potentially causing serious complication or death in babies, especially pre-term infants or infants under 6 months, as well as high-risk older adults.

In 2019, 33 million cases of RSV-associated acute lower respiratory infection were recorded globally, with 101,400 RSV-attributable deaths in children aged 5 years and younger. In adults aged 65 years and above, the estimated global burden of disease in 2015 was 336,000 hospitalisations and 14,100 in-hospital deaths. In Hong Kong, RSV is the leading viral cause of hospitalization due to common respiratory viruses (more than 50% of all cases) in children under the age of one.

RSV disease is caused by two major virus subgroups: RSV A and RSV B. Both subgroups can co-circulate or alternate in predominance from season to season. The bivalent vaccine is unadjuvanted and composed of two preF proteins selected to optimize defense against RSV A and B strains and has been observed to be safe and effective.

The Department of Health's decision is based on the data from two clinical trials: RENOIR for older adults, and MATISSE for newborns and young infants.