

UK marketing authorisation granted for Sanofi Pasteur's Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose ▼ (TIV High Dose)

- * TIV High Dose is approved for the prevention of influenza in people 65 years of age and older,¹ a population that is particularly vulnerable to influenza infection and its complications²
- * National approval process for TIV High Dose could serve as a template for how new product approvals could take place after the UK leaves the European Union
- * UK is the only European country where TIV High Dose is approved

MAIDENHEAD, UK – January 18, 2019 – UK marketing authorisation has been granted for Sanofi Pasteur's Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose (TIV High Dose), which is indicated for active immunisation of people 65 years of age and older against influenza disease.¹ This decision means the UK is the only European country where TIV High Dose is approved.

The UK approval of TIV High Dose followed a national procedure, with Sanofi Pasteur working in collaboration with the UK regulator in an agile and flexible way to gain accelerated assessment of the dossier. The process took just seven months, compared with a standard review time of 12 months for national approvals. This way of working could provide opportunities for faster product approvals after the UK leaves the European Union.

"We are pleased that a UK marketing authorisation has been granted for this vaccine. This approval is a positive step towards increasing the options available for healthcare professionals to help protect people 65 years of age and older against flu in the UK," says Hugo Fry, Managing Director at Sanofi UK. "Sanofi Pasteur is dedicated to supporting public health needs and continues to actively explore several innovative influenza vaccines for the future. We have worked closely with the UK regulator throughout this approval process and are grateful to them for their engaged and agile approach."

Our immune defenses naturally decline with advancing age, which can cause our immune responses to vaccines to diminish.² This natural decline also means that older adults are particularly vulnerable to influenza infection and its complications.² TIV High Dose has therefore been designed specifically to improve protection against influenza compared to standard dose TIV for this population.¹

TIV High Dose is included in the Joint Committee on Vaccination and Immunisation (JCVI) advice on influenza vaccines for the 2019/20 influenza season.

TIV High Dose is already approved for people 65 years of age and older in the United States (US), Canada, Australia and Brazil.

About influenza

Influenza or “flu” is an acute viral infection caused by influenza viruses, which spreads easily from person to person. Flu circulates all year round worldwide but mostly in the winter, which is why it’s sometimes referred to as seasonal flu.³ People at highest risk of severe illness or complications from flu are pregnant women, children under 59 months, the elderly, individuals with chronic health conditions (such as diabetes, or chronic heart or respiratory diseases), and individuals that have a weakened immune system due to conditions such as HIV/AIDS, malignancy or from receiving chemotherapy or steroids.³ Worldwide, annual flu epidemics result in 3 to 5 million cases of severe illness, and 290,000 to 650,000 deaths.³ In industrialised countries most deaths associated with flu occur among people age 65 or older.³

In the UK, fatalities attributable to flu are estimated to range from around 4,000 to 14,000 per year, with an average of around 8,000 fatalities per year, across all age groups.⁴ The 2017/18 winter season showed moderate to high levels of circulating flu in the UK, of which the impact was predominantly seen in older adults, with a consistent pattern of outbreaks in care homes.⁵ Of the 3,454 confirmed, flu-related hospital admissions to intensive care or high-dependency units, 42% of the cases were in those aged 65 years and older.⁵ In addition to considerable evidence of immune responses to vaccination declining with age, over 50% of older people (65 years of age and older) have at least two chronic conditions.⁶ This further increases the likelihood of flu-related complications or worsening of the underlying chronic condition in this population.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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- ⁶ Kingston A, et al. Projections of multi-morbidity in the older population in England to 2035: estimates from the Population Ageing and Care Simulation (PACSim) model. *Age Ageing.* 2018;47(3):374-380.