New, high dose influenza vaccine available to over 65’s this influenza season

*Fluzone® High-Dose will be made available on the National Immunisation Program (NIP) ahead of 2018 influenza season*

Sydney, Australia, 18th February, 2018 – Today Sanofi Pasteur, the vaccines business unit of Sanofi, welcomed news that Fluzone High-Dose will be made available on the NIP for adults aged 65 years of age or older.

Influenza is a contagious respiratory disease caused by different strains of the influenza virus, and can spread rapidly, especially in nursing homes or other institutions.\(^1\) Influenza is much more severe in certain populations, particularly in older adults.\(^1\)

Fluzone High-Dose, registered by the Therapeutic Goods Administration (TGA) in December 2017, is a trivalent, seasonal influenza vaccine designed specifically for adults aged ≥65 years. The vaccine contains four times the amount of antigen for each of the three strains in the vaccine, compared with regular trivalent influenza vaccines. It has been proven to provide increased clinical protection against influenza amongst older adults, compared to standard dose, unadjuvanted, trivalent vaccines.\(^2,3\)

The 2017 influenza season in Australia saw the highest level of influenza activities on record with almost 250,000 laboratory-confirmed influenza cases - three times the number of notifications compared with 2016.\(^4\)

Older adults were most affected by the 2017 influenza season. In NSW alone, 784 aged care residents were hospitalised as a result of multiple influenza outbreaks. Furthermore, 304 residents died due to confirmed cases of influenza and its complications.\(^5\)

“Influenza is a significant cause of illness and regular influenza vaccines have been less effective in older adults, compared with younger adults and children, due to the gradual deterioration of the immune system brought on by natural age advancement,” said infectious disease expert, Professor Raina MacIntyre.

“Any vaccine that can help older people mount a better immune response is a welcome addition ahead of the 2018 influenza season, particularly for older adults, as we look to reduce GP visits and hospitalisations and avoid serious health complications. The high dose vaccine is one of these,” said Professor MacIntyre.

Fluzone High-Dose has been used in the USA since 2009 and was registered in Canada in 2016, with its clinical benefits recognised by the authorities of both countries.\(^6,7\) Australia is the first country outside the Northern American continent in which Sanofi Pasteur has introduced its high dose influenza vaccine.
The benefits of Fluzone High-Dose are supported by robust clinical evidence. The vaccine’s pivotal clinical trial demonstrated that Fluzone High-Dose was 24% more effective in preventing laboratory-confirmed influenza, than the regular trivalent influenza vaccine, in people 65 years of age or older.\(^3\)

In addition to Fluzone High-Dose, Sanofi Pasteur will also supply the Australian Government with FluQuadri\(^\text{TM}\) available to eligible people aged three years and older, and FluQuadri\(^\text{TM}\) Junior, for eligible children aged six months to less than three years.

“Sanofi Pasteur is pleased to supply the Australian Government with Fluzone High-Dose, FluQuadri and FluQuadri Junior, ahead of the 2018 influenza season, said Russell Jacobson, General Manager, Sanofi Pasteur Australia and New Zealand.

“As always, our local priority is to meet the public health needs of all Australians. We are committed to assisting both the Health Department and the Australian community to reduce the impact of influenza now and in the future,” he added.

The enhanced benefits of Fluzone High-Dose, compared with standard dose, unadjuvanted, trivalent influenza vaccine, have been reported in a number of independent, large community studies that were conducted by the US health authorities\(^8,9\) as well as in nursing home settings\(^10,11\).

The safety profile of Fluzone High-Dose is similar to that of regular trivalent influenza vaccines and most people receiving the high dose influenza vaccine had no or minimal adverse events.\(^12\) Some adverse events (e.g. redness at the injection site), which are also reported after regular trivalent influenza vaccines, were reported more frequently after vaccination with Fluzone High-Dose.\(^12\)

Fluzone High-Dose, FluQuadri and FluQuadri Junior will be made available for eligible individuals on the NIP for the 2018 influenza season.

BEFORE PRESCRIBING, PLEASE REVIEW FULL PRODUCT INFORMATION AVAILABLE ON REQUEST FROM SANOFI PASTEUR ON +61 (0)2 8666 2000 OR THE FOLLOWING LINKS:


CONSUMER MEDICINES INFORMATION IS AVAILABLE ON REQUEST FROM SANOFI PASTEUR ON +61 (0)2 8666 2000 OR THE FOLLOWING LINKS:


PBS Information: These products are not listed on the PBS. These products are listed on the National Immunisation Program (NIP). Refer to NIP Schedule.
Fluzone High-Dose Minimum Product Information

**INDICATIONS:** Fluzone High-Dose is indicated for active immunisation against influenza disease caused by influenza virus types A and B contained in the vaccine for use in persons 65 years of age and older.

**CONTRAINDICATIONS:** Known systemic hypersensitivity reactions after previous administration of any influenza vaccine or to any component of vaccine (eggs or egg products). Fluzone High-Dose should be given in accordance with national recommendations as per the current Immunisation Handbook.

**PRECAUTIONS:** Weigh risks and benefits in subjects with a history of Guillain-Barré Syndrome (GBS), or bleeding disorder. Postpone vaccination until after immunosuppressive treatments or resolution of immunosuppressive conditions, and in case of an acute or febrile disease. Pregnancy and lactation – Category C.

**SIDE EFFECTS:** Local reactions: pain, erythema and swelling. Systemic reactions: myalgia, headache, malaise, fever. Very rarely: transient thrombocytopenia, lymphadenopathy, ocular hyperaemia, vasculitis, dyspnoea, Stevens-Johnson syndrome, anaphylaxis and other allergic reactions and neurological disorders such as myelitis, GBS, convulsions (including febrile convulsions) and Bell’s palsy, vomiting and diarrhoea.

Date of first inclusion in the ARTG: 21st December 2017

FluQuadri/FluQuadri Junior Minimum Product Information

**INDICATIONS:** FLUQUADRI indicated for active immunisation of influenza caused by influenza virus types A and B in adults and children aged 3 years and over. FLUQUADRI Junior indicated in children aged 6 months to 35 months inclusive. Dosage and administration: Shake well. For IM injection. Adults and children 3 years of age and over: 0.5mL. Infants and children 6 months to 35 months: 0.25mL. Two doses separated by an interval of 4 weeks recommended for children who are receiving influenza vaccine for the first time.

**CONTRAINDICATIONS:** Known systemic hypersensitivity reactions after previous administration of any influenza vaccine or to any component of vaccine (eggs or egg products), and acute febrile illness.

**PRECAUTIONS:** Weigh risks and benefits in subjects with a history of Guillain-Barré Syndrome (GBS), bleeding disorder or in persons on anticoagulant therapy. Pregnancy and lactation – Category B2. Health authorities recommend vaccination of pregnant women.

**SIDE EFFECTS:** Local reactions: pain, tenderness, erythema, swelling, induration and ecchymosis. Systemic reactions: myalgia, headache, malaise, shivering, fever, irritability, drowsiness, appetite loss and vomiting. Very rarely: transient thrombocytopenia, lymphadenopathy, ocular hyperaemia, vasculitis, dyspnoea, Stevens-Johnson syndrome and other allergic reactions and neurological disorders such as myelitis, GBS, convulsions (including febrile convulsions) and Bell’s palsy.

Date of first inclusion in the ARTG: 2nd December 2014.

Date of most recent amendment: 7th December 2017

Sanofi Pasteur
Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113
+61 (0)2 8666 2000
ABN 31 008 558 807
SPANZ.IFLU.18.02.0042
Date of Preparation: February 2018
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

Additional Notes
Professor Raina MacIntyre received no honoraria for assisting with the preparation of this press release. The opinions expressed in the release are her own. Professor MacIntyre has been briefed by Sanofi on the approved use of this product. Professor Raina MacIntyre has served on Sanofi’s advisory boards and conducted research studies with funding provided by Sanofi, and has also done so with other vaccine manufacturers.

References
2. Sanofi-Aventis Australia Pty Ltd. Fluzone High-Dose Product Information. Date of approval: 21 December 2017.

