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Australians 65 and older become first in the world to access FLUAD® Quad (adjuvanted quadrivalent influenza vaccine) following addition to the National Immunisation Program in 2020¹

- FLUAD® Quad is a new vaccine that is preferentially recommended over the standard quadrivalent influenza vaccines provided on the National Immunisation Program (NIP) in 2020 for Australians aged 65 years and older.²
- People aged 65 years and over have significantly higher rates of hospitalisation and death from influenza compared to younger adults³
- Protecting older Australians against influenza is particularly important in the context of the concurrent COVID-19 pandemic.
- The Government has fast-tracked the approval of FLUAD® Quad to ensure nationwide availability prior to the 2020 influenza season⁴

Embargoed until 0:01am 1 April 2020

Seqirus Australia welcomes the inclusion of FLUAD® Quad (adjuvanted quadrivalent influenza vaccine) on the 2020 National Immunisation Program for adults aged 65 years and older – with Australia the first country in the world to offer this vaccine.¹

FLUAD® Quad is an adjuvanted quadrivalent influenza vaccine.⁵ As with other quadrivalent influenza vaccines, the four antigens have been updated to include the strains recommended by WHO to be representative of those expected to circulate in the Southern Hemisphere winter 2020. These are:

- two influenza type A strains (A/Brisbane/02/2018 (H1N1) pdm09 – like virus and A/South Australia/34/2019 (H3N2) – like virus), and
- two influenza type B strains (B/Washington/02/2019 – like virus and B/Phuket/3073/2013 – like virus).⁵

Influenza can have a substantial negative impact on adults 65 years and older with higher hospitalisation and death rates compared to younger, healthier adults.³ Between 1997 and 2016, 80 per cent of influenza deaths in Australia were in people aged 65 and over.⁶

FLUAD® Quad has been formulated with MF59 adjuvant, which stimulates recruitment of immune cells at the site of injection and helps to trigger production of antibodies in adults aged 65 years and above, who may not always respond as well as younger people to vaccines.^{5,7} The antibody response to FLUAD® Quad is similar to FLUAD® (adjuvanted trivalent influenza vaccine) which is increased when compared to the response to a standard dose vaccine without adjuvant.⁵ Specific antibody levels have not been correlated with protection from influenza.⁵

The NIP listing comes on the back of the Australian Government's move to fast-track the approval of the vaccine to ensure availability in advance of the 2020 influenza season.⁴ Annual vaccination remains the most effective way to prevent influenza infection, and FLUAD Quad is preferentially recommended over standard QIVs for Australians aged 65 years and older.⁸

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The immunogenicity of FLUAD Quad was evaluated in a multi-centre, randomised, double-blind, non-inferiority, comparator-controlled study conducted in subjects 65 years of age and older in the 2017-18 Northern Hemisphere influenza season.⁵

Non-inferiority of the immune response of FLUAD Quad to that of FLUAD (aTIV-1) and aTIV-2 among adults 65 years of age or older was assessed as a co-primary endpoint. Results showed FLUAD Quad was non-inferior for all four influenza strains for both HI antibody titres and seroconversion rates and superior for the alternate B strains.^{5,9}

Adverse events associated with FLUAD Quad include injection site pain, fatigue and headache.⁵ The majority of the adverse events reported were mild or moderate in intensity and resolved within 3 days. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available and persons with a history of anaphylaxis to egg should be vaccinated only in medical facilities with staff experienced in recognising and treating anaphylaxis.⁵

Associate Professor Woodward AM, Director, Aged Care Research and the Head of Memory Clinic at Austin Health said that “this is not the year you want to get flu, nor be complacent about the significant impact influenza has each year on our public health system, particularly the more severe cases that end up in intensive care units (ICU).”

“Vaccinating for flu is always important – but this year it will be particularly critical, and especially for older Australians and those with chronic diseases.”

“While the flu vaccine does not protect against the COVID-19 virus, immunising against the flu - particularly in high-risk groups like those aged 65 and over – may help to reduce the risk of diagnostic uncertainty between flu and COVID-19 and reduce pressure on our health system and ICUs.”

Seqirus Asia Pacific Head of Medical Affairs, Dr Jonathan Anderson congratulated the Federal Government and Minister Hunt for continuing Australia’s world-leading public immunisation program and fast tracking the approval of FLUAD Quad for Australians aged 65 and over.

“Seqirus is proud to continue our partnership with the Australian Government which has enabled us to deliver a world-first launch of our adjuvanted quadrivalent vaccine and further build on our commitment to deliver public health innovation for Australians.”

PBS Information: FLUAD Quad is listed on the National Immunisation Program (NIP) Schedule. Refer to the NIP Schedule.

Please review Product Information before prescribing, available at <https://labeling.seqirus.com/PI/AU/Fluad/EN/Fluad-Product-Information.pdf>

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MINIMUM PRODUCT INFORMATION

FLUAD® QUAD⁵

Inactivated quadrivalent influenza vaccine (surface antigen), adjuvanted, suspension for injection.

APPROVED INDICATION: Active immunisation against influenza in persons 65 years of age and older.

CONTRAINDICATIONS: Known severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine except egg proteins (see 'Clinically Significant Precautions'), or a previous dose of any influenza vaccine.

CLINICALLY SIGNIFICANT PRECAUTIONS: Persons with a history of egg anaphylaxis should be vaccinated only in medical facilities with staff experienced in recognising and treating anaphylaxis. Postpone immunisation in acute febrile illness. Consider potential benefits and risks of giving Flud® Quad if Guillain-Barré Syndrome has occurred within 6 weeks of previous influenza vaccination. Pregnancy Category B2.

CLINICALLY SIGNIFICANT INTERACTIONS: No clinical data on concomitant administration of Flud® Quad with other vaccines are available. Coadministration of the adjuvanted trivalent influenza vaccine Flud® with either PCV-13 or PPV-23 did not show significant interference in antibody response although it induced more frequent local pain. If Flud® Quad needs to be coadministered with another vaccine, use separate injection sites, preferably on different limbs - any adverse reactions may be intensified.

VERY COMMON AND COMMON ADVERSE EVENTS: The overall safety profile of Flud® Quad is similar to Flud®. *Local reactions* including injection site pain, redness and induration. *Systemic reactions* including fatigue, headache, arthralgia and myalgia. The majority of these reactions were mild or moderate in intensity and resolved within 3 days.

DOSAGE AND METHOD OF USE: A single 0.5 mL dose should be administered by intramuscular injection into the deltoid muscle. Gently shake before use. After shaking, the normal appearance is a milky-white suspension. Annual vaccination is recommended.

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Notes to editor:

In relation to this media announcement, no compensation was provided to Associate Professor Michael Woodward and the opinions expressed are his own. Associate Professor Michael Woodward has received payment from Seqirus for consultancy services including acting on Advisory Boards and advising on medical education materials.

About Seqirus:

Seqirus, a CSL company, is a leading provider of essential vaccines and pharmaceuticals. We have served Australia's healthcare needs for over a century and today we develop, manufacture and source medicines that support the health and wellbeing of many thousands of people around the world.

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