14 June 2022

Re: Supply of FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation) under Section 19A of the Therapeutic Goods Act 1989

Dear Healthcare Professional,

The Australian registered product FluQuadri Inactivated Quadrivalent Influenza Vaccine (Split Virion), Influenza virus haemagglutinin 60 mcg, 0.5 mL suspension for injection (AUST R 213963), sponsored by Sanofi-Aventis Australia Pty Ltd, is currently in short supply due to an increase in demand of the universally funded influenza vaccination programs implemented by State Health Departments in Australia.

Sanofi has been able to arrange a supply of FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation) on a temporary basis.

This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until 15 January 2023 for the following indication:

> *FluQuadri is indicated for active immunisation of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluQuadri is indicated for use in adults and children 6 months and older.*

The s19A approved product FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation) is identical in active ingredient, strength and excipient ingredients to the Australian registered product.

An illustration of the presentation is outlined in Table 1 to assist in identifying the different packaging components.

Please refer to the Australian Product Information for FluQuadri Inactivated Quadrivalent Influenza Vaccine (Split Virion), Influenza virus haemagglutinin 60 mcg, 0.5 mL suspension for injection (AUST R 213963) (available at https://www.ebs.tga.gov.au) when prescribing and administering FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation).

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation) should be reported by healthcare professionals and patients to Sanofi on 1800 818 806 or ae@sanofi.com. Alternatively, this information can be reported to the TGA at www.tga.gov.au/reportingproblems.

Please forward this information to relevant staff members in your organisation.

If you would like further information regarding FluQuadri Quadrivalent Influenza Vaccine, Types A and B subvirion, 0.5mL suspension for injection 2022 (International Presentation) please contact:

- For medical enquiries contact Sanofi Medical Information 1800 818 806
- For enquiries relating to supply contact Sanofi Customer Service 1800 829 468

Thank you for your understanding.
Regards,

Dr Iris Depaz
Head of Medical Sanofi Pasteur and Sanofi ANZ Medical Country Lead

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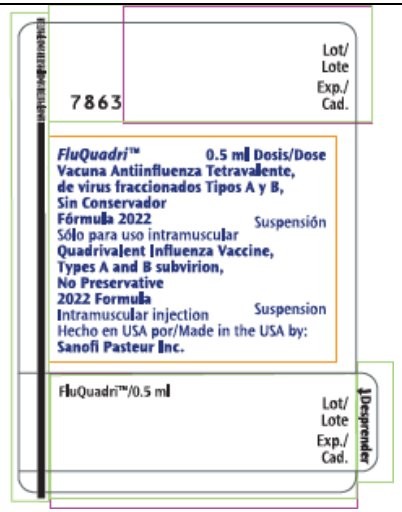
Table 1 – Illustration of packaging components

	Carton	Vial	Leaflet
Standard Export Packaged presentation (English and Spanish)			The leaflet is written in English and Spanish: **FluQuadri™** **Quadrivalent Influenza Vaccine Types A and B subvirion** **2022 Formula** FULL PRESCRIBING INFORMATION: