

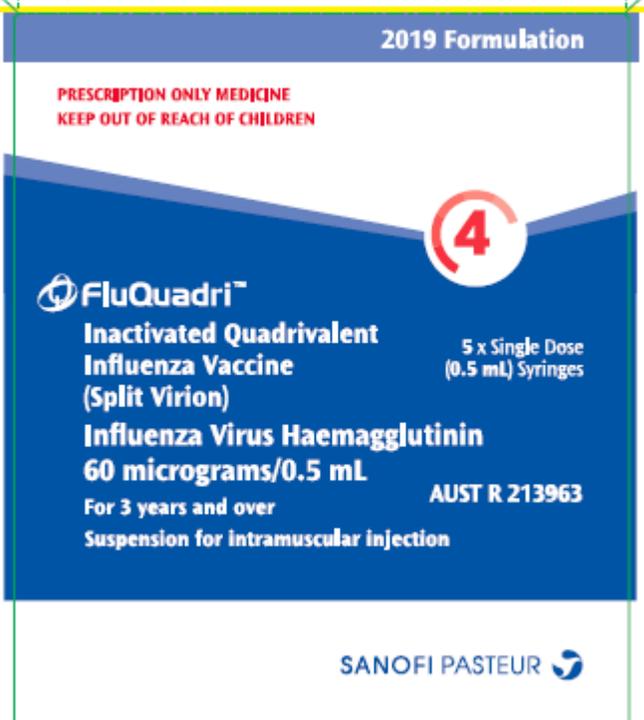
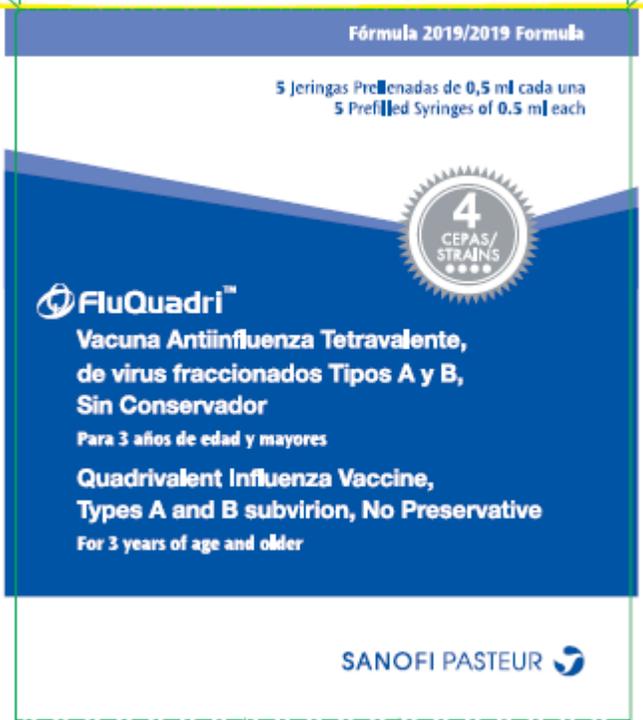
27 May 2019

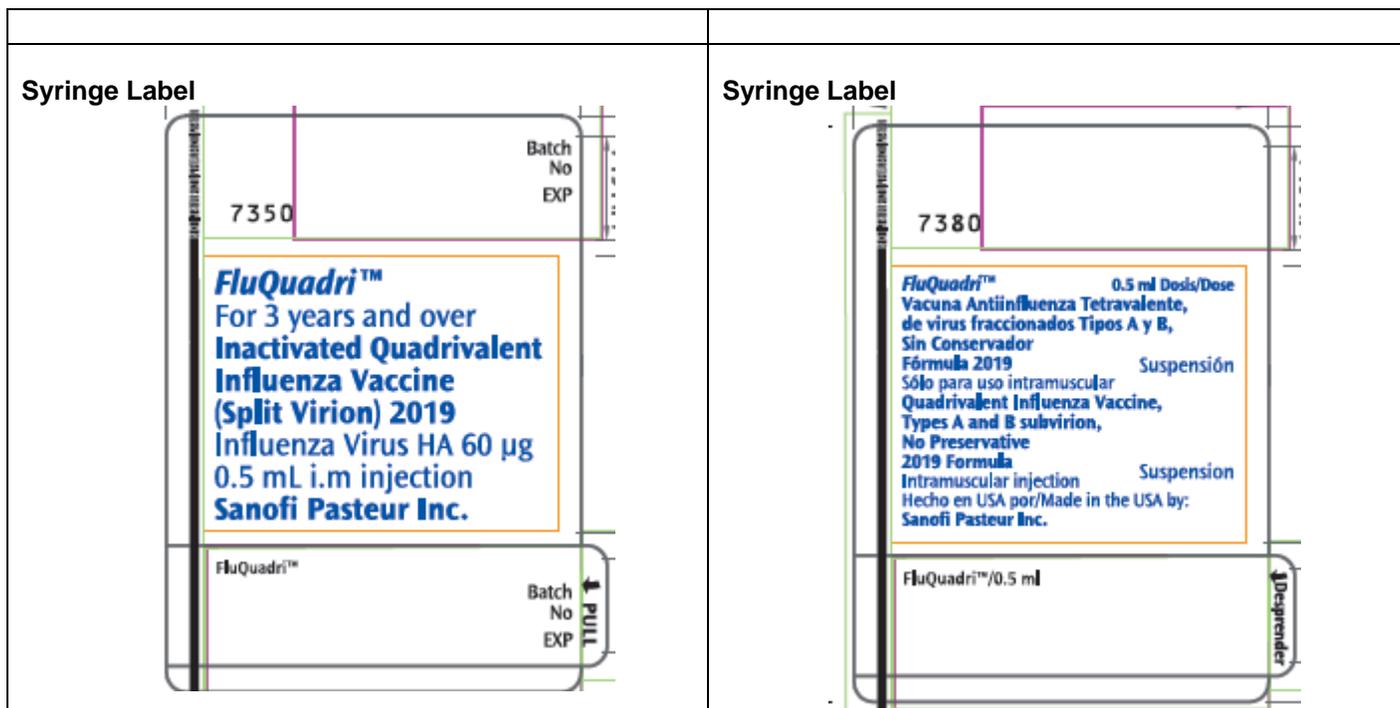
Dear Healthcare Professional

**Additional Supply of FluQuadri under Section 14 of the *Therapeutic Goods Act 1989***

There has been an unprecedented demand for seasonal influenza vaccines this year and this has resulted in a limited availability of influenza vaccines including FluQuadri (manufactured by sanofi pasteur). To address the increase in demand, Sanofi has imported additional doses of FluQuadri for individuals aged 3 years and over. Given that the imported batch (UJ173AA) is packaged using the Standard International labelling, it does not comply with the Australian labelling requirements. It is important to note that the product is the same, the differences that we are noting here are in the labelling and we are writing to you to ensure that you are aware of these differences.

The Standard International labelling is intended for the global market and hence is different to the labelling used in Australia, as highlighted below:

<p style="text-align: center;"><b>Australian labelling</b></p> <p style="text-align: center;"><b>FluQuadri 0.5 mL 3 years &amp; over</b> <b>English</b></p>	<p style="text-align: center;"><b>Standard International labelling</b></p> <p style="text-align: center;"><b>FluQuadri 0.5 mL 3 years &amp; over</b> <b>English and Spanish</b></p>
<p><b>Front panel carton</b></p>  <p>The image shows the front panel of a FluQuadri 2019 Formulation carton. At the top, it says '2019 Formulation'. Below that, in red, it says 'PRESCRIPTION ONLY MEDICINE' and 'KEEP OUT OF REACH OF CHILDREN'. The main body is blue with a white circle containing the number '4'. Text includes: 'FluQuadri™ Inactivated Quadrivalent Influenza Vaccine (Split Virion) Influenza Virus Haemagglutinin 60 micrograms/0.5 mL For 3 years and over Suspension for intramuscular injection'. It also mentions '5 x Single Dose (0.5 mL) Syringes' and 'AUST R 213963'. The Sanofi Pasteur logo is at the bottom.</p>	<p><b>Front panel carton</b></p>  <p>The image shows the front panel of a FluQuadri 2019/2019 Formula carton. At the top, it says 'Fórmula 2019/2019 Formula'. Below that, it says '5 Jeringas Prellenadas de 0,5 ml cada una' and '5 Prefilled Syringes of 0.5 ml each'. The main body is blue with a white circle containing the number '4' and '4 CEPAS/STRAINS'. Text includes: 'FluQuadri™ Vacuna Antiinfluenza Tetravalente, de virus fraccionados Tipos A y B, Sin Conservador Para 3 años de edad y mayores Quadrivalent Influenza Vaccine, Types A and B subvirion, No Preservative For 3 years of age and older'. The Sanofi Pasteur logo is at the bottom.</p>



The package leaflet available in each carton is written in English and Spanish. It states that FluQuadri is approved for use in persons 6 months of age and available in both 0.25 mL and 0.5 mL presentations (as is the case in some international markets). You should note that in Australia, 0.25 mL presentation is available as FluQuadri Junior for use in children aged 6 to 35 months. Consequently the FluQuadri batch UJ173AA should not be used in this population.

Should you have any questions relating to this product, please call Sanofi Pasteur Medical Information at 1800 818 806.

Thank you for your understanding.

Regards,

Dr. Christian T. Felter, MD  
 Head of Medical, Sanofi Pasteur Australia and New Zealand