

Sanofi Pasteur Mallards Reach, Bridge Avenue, Maidenhead, Berkshire, SL6 1QP

11th January 2019

Dear Healthcare Professional,

Supply of Standard Export pack of Quadrivalent Influenza Vaccine (split virion, inactivated) vsuspension for injection in a prefilled syringe PL 46602/0017 - Lot R3J824V, Expiry 31/08/2019 – Single Packs

Due to higher demand for our Quadrivalent Influenza Vaccine (split virion, inactivated) than anticipated, we have obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply the above batch of stock which is a Standard Export packaging. These packs are labelled with Lot number R3J824V with an expiry date of 31/08/2019.

The product supplied in the Standard Export packaging is identical to the product authorised for use in the UK apart from the packaging.

There are two languages on each component of the Standard export pack: carton, label and leaflet (English and Spanish).

Also, the tradename is different, on the UK pack the tradename is 'Quadrivalent Influenza Vaccine (split

virion, inactivated)'and on the Standard export pack the tradename is 'VaxigripTetra' $oldsymbol{
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Please explain to patients being administered with stock from Standard Export packaging that these packs are approved for use in the UK.

If you have any questions, please contact the Sanofi Pasteur Medical Information Department on 0845 372 7101.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Cards website - <u>https://yellowcard.mhra.gov.uk/</u> or via the Yellow Card app available from the Apple App Store or Google Play Store. When reporting a suspected ADR to a vaccine, please provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Adverse events should also be reported to Sanofi Pasteur telephone number 0800 0902314.

Yours faithfully,

To be signed at approval

lan GRAY Head of Medical Sanofi Pasteur