

Date: 29 November 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fluad Tetra (Influenza vaccine (surface antigen, inactivated, adjuvanted)) 0.5ml 10x1 PFS: Interim Supply to GREAT BRITAIN to Mitigate Supply Disruption

Dear Healthcare Professional,

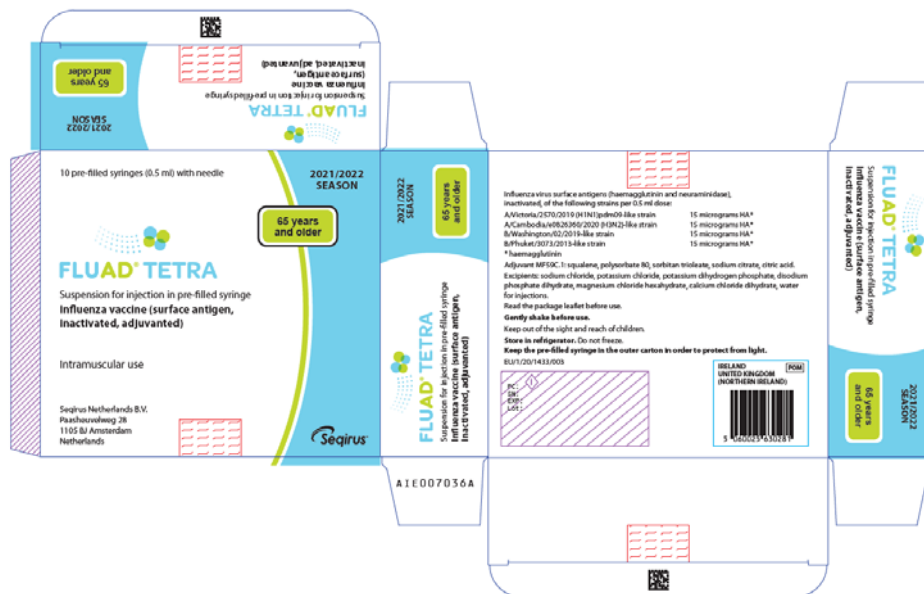
Summary: To support Covid vaccine co-administration and increased demand, Seqirus is currently importing additional Fluad Tetra (Influenza vaccine (surface antigen, inactivated, adjuvanted)) 0.5ml 10x1 PFS from the EU to Great Britain.

To support an increase in demand to support co-administration of influenza vaccine with Covid vaccine, Seqirus has obtained approval from the MHRA to supply Great Britain with Fluad Tetra packed for the Republic of Ireland/Northern Ireland (batch number 8636C1A; batch size 9,958 packs). The product is expected to be on the Great Britain market from approximately 30 November 2021 to 31 May 2022.

Please note the following:

- This product is licensed in the UK under PLGB 47991/0002.
- The product from Republic of Ireland/Northern Ireland has the same formulation as the Great Britain product
- The product from Republic of Ireland/Northern Ireland is manufactured according to the same manufacturing process and quality controls as the Great Britain product.
- There are minor differences between the Republic of Ireland/Northern Ireland and Great Britain product information. Key differences are the address of the registered manufacturer and the license number, also the inclusion of reporting details for Republic of Ireland. Please ensure the GB Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the Great Britain approved PIL supplied with the Republic of Ireland/Northern Ireland packs. Discard the Republic of Ireland/Northern Ireland leaflet in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/product/11679> or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Fluad Tetra and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information about Fluad Tetra, please contact MedInfo at 01748 828816 or Seqirus@eu.propharmagroup.com

Yours faithfully,

Kaush Gandhi

Kaush Gandhi
Director, Marketing UK & Ireland Cluster
Seqirus UK Ltd