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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

ZOONOTIC FLU VAX PFS 25G25 RNS 10X1.
Adjuvanted Zoonotic Influenza Vaccine (Surface Antigen, Inactivated)-
Seqirus suspension for injection in pre-filled syringe.
Zoonotic influenza vaccine (H5N8) (surface antigen, inactivated, adjuvanted).

Dear Healthcare Professional,

Summary: Seqirus is supplying Zoonotic Influenza vaccine, equivalent to Adjuvanted Influenza Vaccine suspension for injection in pre-filled syringes to be distributed within the United Kingdom market.

To ensure adequate supply, Seqirus has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply United Kingdom with Adjuvanted Zoonotic Influenza Vaccine packed for United Kingdom. Batch numbers as follows;
9712411P1 (84,440 doses), 9733411P1 (85,833 doses), 9733511P1 (85,894 doses), 9733611P1 (84, 349 doses), 9744111P1 (87,288 doses), 9744211P1 (28,484 doses), 9744021P1 (30,697 doses), 9744031P1 (4250 doses) and 9744031P2 (23,632 doses); which is expected to be on the Great Britain market from 13-Jan-25 to 31-0ct-26 (expiry date).

Please note the following:

- This product is considered licensed in the UK under PLGB 47991/0013.
- There are no changes within the formulation of the product.
- There are no changes within the manufacturing process and quality controls of the product.
- The Key difference is the change in the registered PI of the zoonotic influenza vaccine for extension of age indication within the relevant sections of the SmPC and the PIL, which has been extended to 6 months and above from the original UK age indication of 18 years and upwards.
- The leaflet packed in the cartons contains the therapeutic indication text, which was correct at the time of manufacture and packing. This indicates age from 18 years and upwards, as follows:
  "Adjuvanted Zoonotic Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe is a vaccine for use in adults from 18 onwards, intended to be given in the context of outbreaks of zoonotic influenza viruses (coming from birds) with pandemic potential to prevent flu caused by viruses similar to the vaccine strain reported in section 6."
- In November 2024, the MHRA approved a variation to extend the age indication to 6 months and above and the relevant sections of the PIL were updated as follows:
  "Adjuvanted Zoonotic Influenza Vaccine Seqirus H5N8 is a vaccine for use in individuals 6 months of age and older, intended to be given in the context of outbreaks of zoonotic influenza (coming from birds) to prevent flu caused by H5 subtype influenza A viruses."
- An extra supply of the updated leaflets will be provided, separate to the carton. Please refer to the UK approved PIL supplied with UK Zoonotic Influenza cartons. Discard the original UK Zoonotic carton leaflet in the pack.
- For additional copies of the leaflet, please refer to:
  https://www.medicines.org.uk/emc/files/pil.16015.pdf or contact the company contact point (see below).

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
Please continue to report suspected adverse drug reactions (ADR's) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product license number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point
If you have any questions about this letter or require more information about Adjuvanted Zoonotic Influenza Vaccine, please contact Seqirus Medical Information at 01748 828816 or Seqirus@eu.propharmagroup.com

Yours faithfully,

Alexander Kennedy *PhD*
Associate Director Medical Affairs–Pandemic Preparedness
Seqirus UK Ltd