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30th November 2023

Reference: Recall of specific batches of Fluenz Tetra Nasal Spray Suspension, Influenza vaccine (live attenuated, nasal)

Dear Healthcare Professional,

Class 3 medicines recall: Specific batches of Fluenz Tetra Nasal Spray Suspension, Influenza vaccine (live attenuated, nasal), PLGB 17901/0324

AstraZeneca UK Limited in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you that following routine stability analysis, the printed expiry date for the listed batches of Fluenz Tetra nasal spray suspension is incorrect. Due to the outcome of the ongoing analysis, the expiry dates for batches TH2127, TH2127B, TH3110, TH3110B, TJ2290 and TJ2290B need to be reduced by up to 5 days as a precautionary measure. The products may be safely administered up to the amended expiry date. The amended expiry dates are included in the table below.

Batch Number	Printed Expiry Date	Amended Expiry Date	Pack Size	First Distributed
TH2127	28-Dec-2023	23-Dec-2023	10 sprayers	30-Aug-2023
TH2127B	28-Dec-2023	23-Dec-2023	10 sprayers	30-Aug-2023
TH3110	01-Jan-2024	28-Dec-2023	10 sprayers	01-Sep-2023
TH3110B	02-Jan-2024	29-Dec-2023	10 sprayers	01-Sep-2023
TJ2290B	10-Jan-2024	05-Jan-2024	10 sprayers	11-Sep-2023
TJ2290	11-Jan-2024	06-Jan-2024	10 sprayers	11-Sep-2023

Active Pharmaceutical Ingredient: Reassortant influenza virus (live attenuated), details relating to the four strains can be found in the Summary of Product Characteristics (SmPC): https://www.medicines.org.uk/emc/product/3296/smpc

Advice for healthcare professionals
The advice for healthcare professionals includes specific actions on continuing to use the vaccines up until the amended expiry date and also to return any unused stock after the amended expiry date has passed.

- Please ensure the above batches are fully administered within the amended expiry dates listed above. Disseminate this information within 5 days, ensure any of the above batches are identified and used within the amended expiry date. Except for the updated expiry date, there are no other changes made to the product information.

- **Place stock that has not been administered by the amended expiry date in quarantine.** All remaining stock in quarantine should be returned to your supplier using your supplier's approved process. For stock return enquiries in Great Britain, please contact Movianto Customer Care on 01234 587 207 or Moviantouk.NHSCC@movianto.com. For stock return enquiries in Northern Ireland, please email contact.nireland@movianto.com.

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- AstraZeneca can assure full effectiveness up to and including the amended expiry date. The quality, safety and efficacy of Fluenz Tetra is not affected, and parents/care givers do not need to be concerned about their child's vaccination.

- Please ensure all relevant staff are made aware of the content of this letter.

Call for Reporting
Please report suspected adverse drug reactions (ADRs) 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▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

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.

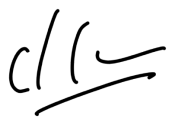
The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue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

About Fluenz Tetra
Fluenz Tetra is indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. The use of Fluenz Tetra should be based on official recommendations.

Company Contact Point
For further information on this matter or medical information enquiries, contact AstraZeneca Medical Information medical.informationUK@astrazeneca.com or call 0800 783 0033.

Yours sincerely,



Edward Piper

Director of Medical and Scientific Affairs,
AstraZeneca