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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

30 November 2023

Dear Healthcare Professional,

**DRUG ALERT CLASS 3 DRUG ALERT 39 2023 – CLASS 3 MEDICINES RECALL -
DISSEMINATE AND PLAN WITHIN 5 DAYS, ENSURE IMPACTED BATCHES ARE
IDENTIFIED EARLY – ASTRA ZENECA UK LTD FLUENZ TETRA NASAL SPRAY
SUSPENSION**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team





M E D I C I N E S R E C A L L

CLASS 3 MEDICINES RECALL

Disseminate and Plan Within 5 Days, Ensure Impacted Batches Are Identified Early
Pharmacy/Wholesaler Level Recall

Date: 30 November 2023

EL (23)A/389

Our Ref: MDR 298-09/23

Dear Healthcare Professional,

AstraZeneca UK Ltd.

Fluenz Tetra nasal spray suspension

PLGB 17901/0324

SNOMED Code 27114211000001105

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>

Brief description of the problem

AstraZeneca UK Ltd. has informed the MHRA 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 above.

Advice for healthcare professionals

The advice for healthcare professionals includes specific actions on continuing to use the vaccines up until the amended expiry date. Disseminate this information within 5 days, ensure any of the above batches are identified and used within the amended expiry date. After the amended expiry date, any unused products should be quarantined for return. This timeframe relates to acknowledging the information contained within the alert and ensuring that no vaccines are administered after the amended expiry date.

- Healthcare professionals, specifically those involved in the administration of this vaccine should continue to use the vaccine as directed. The vaccines may be administered safely



Medicines & Healthcare products Regulatory Agency

up to the amended expiry date. Batches administered before the amended expiry date are fully effective.

- Except for the amended expiry date, there are no other changes to the product information.
- Any stock that has not been administered before the amended expiry date should be quarantined. All quarantined stock should be returned to your supplier using your supplier's approved process. For stock return enquiries, please contact Movianto Customer Care on 01234 587207 or Moviantouk.NHSCC@movianto.com; For stock return enquiries in Northern Ireland, please email contact.nireland@movianto.com.

Advice for patients and their representatives

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. Fluenz Tetra is administered under the supervision of a healthcare professional. Healthcare professionals will ensure that these batches are not used after the amended expiry date; if there is any concern, discuss this alert with the administering healthcare professional. The products may be safely administered up to the amended expiry date. In the unlikely event that you receive the vaccination after the amended expiry date, it should not cause harm, but it may be less effective against one of the four strains of flu included in the vaccine.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact AstraZeneca Medical Information medical.informationUK@astrazeneca.com or call 0800 783 0033.

Fluenz Tetra remains available to order by NHS providers of the children's flu programme in England and Wales via the [ImmForm](#) website (Helpdesk: 0207 183 8580 or Helpdesk@immform.org.uk).

Please refer to your respective health departments in Scotland and Northern Ireland for guidance on obtaining more vaccine if required.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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