

**Professor Sir Michael McBride**  
**Chief Medical Officer**

**Mrs Cathy Harrison**  
**Chief Pharmaceutical Officer**



## **HSS (MD) 61/2021**

### **For Action:**

Chief Executives, Health and Social Care  
Board/HSC Trusts

Family Practitioner Service Leads, Health and  
Social Care Board

GP Medical Advisers, Health and Social Care Board

All General Practitioners and GP Locums  
Medical and Nursing Directors, HSC Trusts (*for  
onward distribution to all independent prescribers*)  
Directors of Pharmaceutical Services, Health and  
Social Care Board/Trusts

### **PLEASE SEE ATTACHED FULL CIRCULATION LIST**

Dear Colleague

## **LABELLING OF FLUENZ TETRA® VACCINE DURING 2021/22 INFLUENZA SEASON**

### **ACTION REQUIRED**

#### **Childhood Flu Vaccination Programme**

Chief Executives must ensure this information is drawn to the attention of all staff involved in the seasonal childhood influenza vaccination programme, including:

- school health teams, health visitors, community children nurses, and paediatricians
- physicians managing patients with chronic medical conditions, oncologists, geriatricians, district nurses, treatment room nurses

The HSCB must ensure this information is cascaded to all General Practitioners, and practice managers for onward distribution to all staff involved in the seasonal childhood flu vaccination programme.

### **Introduction**

1. The purpose of this letter is to provide information about the packaging of the Fluenz Tetra® vaccine for the annual seasonal childhood influenza vaccination programme for 2021/22.

## Detail

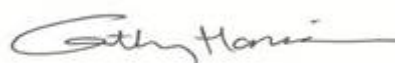
2. To ensure continuity of supply of Fluenz Tetra® in Northern Ireland for the duration of the 2021/2022 vaccination programme, Fluenz Tetra® vaccine stock you receive at the start of the 2021/22 influenza season may be packaged in GB packs. Fluenz Tetra® doses delivered later in the season will be packaged specifically for Northern Ireland.
3. Please note that the product formulations between the Great Britain and Northern Ireland stock are identical and they are both indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age.
4. Differences in packaging are set out in detail in **Annex A** and include:
  - **Carton:** The Name and Address of the Marketing Authorisation Holder and Marketing Authorisation Numbers differ.
  - **Label:** The Great Britain pack is supplied with a one-part label and the Northern Ireland pack is supplied with a three-part label.
  - **Patient Information Leaflet (PIL):** minor differences exist between the Northern Ireland PIL and the Great Britain PIL that will be supplied with the pack.
5. GB packs are supplied via a labelling exemption under article 63(3) of Council Directive 2001/83/EC. Although it will not be possible to decommission GB packs under FMD provisions, MHRA have approved the supply of these licensed packs.

Further details can be found at **Annex A**.

Yours sincerely



**Prof Sir Michael McBride**  
**Chief Medical Officer**



**Mrs Cathy Harrison**  
**Chief Pharmaceutical Officer**

### **Circulation List**

Executive Medical Director/Director of Public Health, Public Health Agency (for onward distribution to all relevant staff)

Director of Nursing, Public Health Agency

Directors of Pharmacy HSC Trusts

Director of Social Care and Children, HSCB

Family Practitioner Service Leads, Health and Social Care Board (for cascade to GP Out of Hours services)

Medical Directors, HSC Trusts (for onward distribution to all Consultants, gynaecology, hepatology, A&E staff, hospital pharmacy, and sexual health/family planning centres)

Nursing Directors, HSC Trusts (for onward distribution to all Community Nurses, and Midwives)

RQIA (for onward transmission to all independent providers including independent hospitals)

Medicines Management Pharmacists, HSC Board (for cascade to prescribing advisers)  
Regional Medicines Information Service, Belfast HSC Trust  
Regional Pharmaceutical Procurement Service, Northern HSC Trust  
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB  
Professor Sonja McIlfatrick, Head of School of Nursing, University of Ulster  
Siobhan Murphy, CEC  
Donna Gallagher, Open University  
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU  
Professor Colin McCoy, Head of School, School of Pharmacy, QUB  
Professor Colin Adair, Postgraduate Pharmacy Dean, NI Centre for Pharmacy  
Learning and Development, QUB  
Joe Brogan, Assistant Director of Integrated Care, HSCB  
Michael Donaldson, Head of Dental Services, HSCB (for distribution to all  
General Dental Practitioners)  
Raymond Curran, Head of Ophthalmic Services, HSCB (*for distribution to Community  
Optometrists*)  
Trade Union Side  
Clinical Advisory Team  
Louise McMahon, Director of Integrated Care, HSCB

This letter is available on the Department of Health website at  
[https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-  
advice/hssmd-letters-and-urgent-communications](https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications)



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**Direct HealthCare Professional Communication  
Fluenz® Tetra nasal spray suspension, Influenza vaccine (live attenuated,  
nasal): supply of Great Britain-labelled stock in Northern Ireland**

**August 2021**

**Supply of Fluenz Tetra [Influenza Vaccine (live attenuated, nasal)] to Northern Ireland**

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), AstraZeneca will now supply Great Britain-labelled Fluenz Tetra nasal spray suspension, Influenza vaccine (live attenuated, nasal) stock to Northern Ireland, in addition to the usual Northern Ireland-labelled Fluenz Tetra stock.

This action was taken to ensure continuity of supply of Fluenz Tetra in Northern Ireland for the duration of the 2021/2022 vaccination programme. AstraZeneca can confirm that the product formulations between the Great Britain and Northern Ireland stock are identical and they are both indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. The Fluenz Tetra Northern Ireland Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) are available electronically at:

<https://www.emcmedicines.com/en-gb/northernireland/medicine?id=8e0d8d94-c0ec-40a3-8b9e-1f315f16edd2&type=smpc>

Please note that some minor differences do exist between the Northern Ireland PIL and the Great Britain PIL that will be supplied with the pack. The differences are detailed as follows:

- The Yellow Card Scheme reporting details for Great Britain and Northern Ireland are the same. However the Northern Ireland leaflet also includes reporting details for Ireland and Malta.
- The Marketing Authorisation Holder and Manufacturer in the Great Britain PIL differs from that in the Northern Ireland PIL.
- The Great Britain PIL does not contain the contact details of the local representative of the Marketing Authorisation Holder. These details are included in the Northern Ireland PIL and are as follows:

United Kingdom (Northern Ireland), AstraZeneca UK Ltd  
Tel: +44 1582 836 836

- The Great Britain PIL includes information on the Royal National Institute of the Blind (RNIB) service which provides an alternative version of the statutory information for patients in Great Britain. This information is not present in the Northern Ireland PIL, however, the RNIB service is available to all UK patients.

Available options for Northern Ireland patients:

- Contact the local representative on 01582 836 836 to request assistance with the RNIB services.
- Contact the RNIB service directly on 0800 198 5000.

There are also minor differences on the Great Britain and Northern Ireland carton and label. The key differences are as follows:

- **Carton:** The Name and Address of the Marketing Authorisation Holder and Marketing Authorisation Numbers differ.
- **Label:** The Great Britain pack is supplied with a one-part label and the Northern Ireland pack is supplied with a three-part label.

**Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, 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, treatment dates and product brand name.

If you have any queries regarding this product or information in this letter, please contact AstraZeneca Medical Information on 0800 783 0033.

Yours sincerely,



**Dr Alexander de Giorgio-Miller**  
Country Medical Director  
Vice President, AstraZeneca UK