



## Live attenuated influenza vaccine (LAIV) for the UK childhood flu programme

### Background

Live attenuated influenza vaccine (LAIV) has been used in the UK since 2013 to protect children against infection with influenza. The vaccine is the preferred product for children in flu “at-risk” groups aged from 2 to 17 years (inclusive) and used as part of the routine children’s programme delivered in schools and general practices.

The vaccine was chosen for children because of its good safety profile, superior performance compared with inactivated flu vaccines and ease of administration. LAIV is manufactured by AstraZeneca/Medimmune and has been sold in many countries for over 10 years. Only one LAIV vaccine is available, marketed as Fluenz Tetra® for the UK and EU market, and FluMist® Quadrivalent for the US market. Fluenz Tetra® and FluMist® Quadrivalent are the same product but in different packaging.

### Stocks of FluMist® Quadrivalent will be provided as well as Fluenz Tetra® this season

In agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), AstraZeneca is supplying two batches of the US labelled FluMist® Quadrivalent to the UK market in addition to the usual UK labelled Fluenz Tetra® stock. FluMist® Quadrivalent is fully licensed for use in the UK (in accordance with the Fluenz Tetra® licence). This action has been taken due to a shortage of Fluenz Tetra® supply to meet the timelines for the 2015/2016 vaccination programme in the UK. There will be sufficient FluMist® Quadrivalent stock to fulfil the requirements of the vaccination programme.

An explanatory letter from AstraZeneca will be available from [weblink 1](#) from the 23<sup>rd</sup> October.

Fluenz Tetra® and FluMist® Quadrivalent are pharmaceutically identical and FluMist® Quadrivalent is fully licensed for use in the UK (in accordance with the Fluenz Tetra® licence). Some differences exist between the packaging of Fluenz Tetra® and FluMist® Quadrivalent. In addition, there are differences between the US Prescribing Information (USPI) and the UK Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC). In agreement with the MHRA, all FluMist® Quadrivalent packs will be therefore supplied with a UK Patient Information Leaflet (PIL) for Fluenz Tetra®, the USPI should not be used. The Summary of Product Characteristics (SmPC) and PIL are also available electronically at [weblink 2](#).

As these are the same vaccine, both are indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. In the US LAIV is licensed up to the age of 49 years. In the UK LAIV is only licensed for those aged from 24 months to less than 18 years of age.

## Expiry date

To ensure timely supply, changes in the supply schedule were required. This has resulted in a mismatch between the actual expiry date and that printed on the packaging and labelling. The two batches of FluMist® Quadrivalent being supplied (FL2113 & FL2118) must not be used after the 24<sup>th</sup> February 2016.

**This does not affect the safety, quality or efficacy of the batches.**

In agreement with the MHRA, a pre-planned withdrawal of any unused stock of FluMist® Quadrivalent will begin on the 25<sup>th</sup> January 2016. This will help ensure that no time-expired vaccine remains in circulation. AstraZeneca's logistics provider, Movianto, will contact you to arrange collection. Please quarantine any unused FluMist® Quadrivalent ahead of the 24<sup>th</sup> February 2016. This should avoid accidental administration prior to collection.

Batches of UK labelled Fluenz Tetra® will not be subject to the withdrawal and may be used up to the expiry date stated on the carton and nasal applicator.

## FluMist® Quadrivalent availability

FluMist® Quadrivalent will be distributed once existing stocks of Fluenz Tetra® have been delivered to the field.

## Ordering FluMist® Quadrivalent

FluMist® Quadrivalent can be ordered in exactly the same way as Fluenz Tetra® using the Immform website. You will not be able to choose between the two vaccines and only one option will be available at any one time. In order to preserve stocks of both Fluenz Tetra® and FluMist® Quadrivalent, it is very important that you only order what you need for your expected usage over the next 2 weeks. Please DO NOT over-order, or overstock vaccine fridges. Careful management of vaccine stock is essential to avoid vaccine wastage and ensure that we are able to offer vaccine to all eligible children.

In the event of a cold chain failure quarantine the stock. DO NOT DISCARD IT OR USE IT. You should consult 'Responding to cold chain failures involving the live attenuated intra-nasal influenza vaccine (LAIV)' available at [weblink 3](#).

**Children already consented to receive Fluenz Tetra® do not need to be re-consented to receive FluMist® Quadrivalent**

This is because Fluenz Tetra® and FluMist® Quadrivalent are pharmaceutically identical live attenuated influenza vaccines (LAIV) and are therefore interchangeable.

## The National PGD

The initial template PGD written and clinically approved by PHE mentioned only Fluenz Tetra® by name. Therefore the PGD has been amended to a live attenuated influenza vaccine PGD which mentions both Fluenz Tetra® and FluMist® Quadrivalent by name, and is available from [weblink 4](#). However immunisers should be aware that this document is a template only.

Before this PGD can be lawfully used, it must be authorised by NHS England and then signed by the individual user and their authorising manager.

## Administration of FluMist® Quadrivalent

FluMist® Quadrivalent should be administered in exactly the same way as Fluenz Tetra®. A training slide set for influenza immunisation is available via [weblink 5](#).

## Recording use of FluMist® Quadrivalent on the clinical system

Where a child has been vaccinated using Fluenz Tetra® vaccine there is no change to the coding requirements. There is no specific Read code for FluMist® Quadrivalent, but this vaccine can be recorded using the usual approach on the GP system (either “Influenza vaccine (Live attenuated)” or “Fluenz Tetra®”).

As with all vaccines, it is very important to record the batch number and expiry date.

## Vaccine uptake monitoring and reporting

Provided the use of FluMist® Quadrivalent is recorded as set out above, vaccine uptake reporting to child health records departments and/or PHE will be unaffected.

### Web links

web link 1	<a href="http://www.fluenztetra.co.uk/">http://www.fluenztetra.co.uk/</a>
web link 2	<a href="https://www.medicines.org.uk/emc/medicine/29112">https://www.medicines.org.uk/emc/medicine/29112</a>
web link 3	<a href="https://www.gov.uk/government/publications/live-attenuated-influenza-vaccine-responding-to-cold-chain-failures">https://www.gov.uk/government/publications/live-attenuated-influenza-vaccine-responding-to-cold-chain-failures</a>
web link 4	<a href="https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd">https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd</a>
web link 5	<a href="https://www.gov.uk/government/publications/national-flu-programme-training-slide-set-for-healthcare-professionals">https://www.gov.uk/government/publications/national-flu-programme-training-slide-set-for-healthcare-professionals</a>