**Background and Interpretation:**

In the 2019/20 flu season, flu vaccine is being offered to all primary school-aged children and any children from six months of age in clinical risk groups. The flu vaccine that should be offered to most children in the eligible cohort groups is a live attenuated influenza intranasal vaccine (LAIV). It contains an attenuated (weakened) vaccine virus that is also cold adapted so that it cannot cause the disease that it protects against. Only one LAIV vaccine (manufactured by AstraZeneca/MedImmune) is available and is marketed as Fluenz Tetra for the UK and EU market.

AstraZeneca is delaying their delivery of some batches of the childhood nasal spray flu vaccine (Fluenz Tetra®) due to be delivered to PHE in November. This is due to an ‘invalid’ test result in its routine quality testing process which need to be repeated before these batches of vaccine are released by the independent regulator. This is not related to the safety or the efficacy of the vaccine itself, which has passed all the other tests. Although we anticipate that this issue will be resolved quickly; there will be an unavoidable delay to the release of some stock, which may have a knock-on effect on the release of vaccine through ImmForm. It does not affect batches of the vaccine already distributed, or those currently available to order and use for the 2019/20 season.

From Friday 18 October, GPs have been able to order sufficient LAIV vaccine to vaccinate up to 20% of their 2-3 year olds and under-18 at-risk practice population. This will provide most practices with just under half of the vaccine doses they are likely to require for their eligible patients. Recommendations are being made below on how to prioritise the use of LAIV within General Practice.

School providers have been able to order LAIV for over two weeks and school vaccination should continue as planned. PHE will be closely managing the amount of stock available for GPs to order over the next few weeks. If AstraZeneca notify us of further delays with LAIV then PHE, NHS E/I and DHSC will consider further additional measures, in order to prioritise particular groups of children.

Inactivated quadrivalent influenza vaccine for children (QIVe) is supplied centrally by PHE for those aged under two years and for older children in whom LAIV is contraindicated. This vaccine has been available for ordering for some weeks.

The delay does not currently impact on vaccinations for at-risk adults or those aged over 65 years which is already underway in GP surgeries and pharmacies:

**Implications for PHE Centres**

Screening and Immunisation teams in PHE centres are likely to receive calls from GPs and other providers concerned about the delay.

**Implications for PHE sites and services**

Other sites should be aware of the issue and refer calls to the local Screening and Immunisation team.
**Recommendations to PHE centres**

Screening and Immunisation teams are asked to liaise with the local NHS to ensure the recommendations below are cascaded to local GPs. Please continue to liaise with local schools providers to get intelligence on stock levels for the schools programmes.

**Recommendations for General Practitioners**

GPs are requested to implement the seasonal influenza programme as outlined in the Direct Enhanced Service Specification (https://www.england.nhs.uk/wp-content/uploads/2019/03/dess-sfl-and-pneumococcal-1920.pdf). As part of this GPs are required to call in those children who are eligible for flu vaccination, and to undertake recall for those children in clinical risk groups for influenza. Because of the phasing of supplies PHE recommends planning the childhood vaccination programme using following priorities:

- Children in high risk groups aged 6 months to 2 years – these children should be called and offered quadrivalent inactivated influenza vaccine (QIVe)
- Children in high risk groups from 2 to 18 years should be prioritised and offered LAIV (unless contraindicated).
  - those aged 2-3 years and age 11-18 years should be called in and offered LAIV or a suitable quadrivalent influenza vaccine (QIV)
  - those of primary school age (4-10 years) will be invited through schools, but should be vaccinated with LAIV or QIV if they choose to present in general practice
  - Where a practice does not have LAIV available, vaccination of children in high risk groups should not be delayed and a suitable QIV should be offered as an alternative.
- Healthy children aged 2-3 years should be called and offered LAIV as the practice receives stock. Two year olds who are receiving vaccine for the first season are a higher priority than 3 year olds.

Responsible ordering will help support the direction of stock to those with greatest immediate need as it becomes available. Practice staff are asked to only order vaccine needed for the forthcoming week, even if this is below the maximum quota and to avoid stockpiling. Close adherence to the vaccine storage in the cold chain is essential to avoid vaccine wastage.


An information leaflet is being developed for parents to explain which children are eligible for vaccination and where this will be delivered and will be posted shortly on the PHE website.

**Implications and recommendations for local authorities**

- Directors of Public Health (DsPH) should be aware of the potential interruption of the supply of Fluenz Tetra and the possible delay in the flu vaccination programme for children in their local authority area.
- DsPH should be aware in the event of a delay in the delivery of stocks of Fluenz Tetra, a prioritisation protocol will be implemented to ensure the best use of the supplies.

**References/ Sources of information**

1. Influenza: the green book, chapter 19