NHS England Gateway Reference: 08443

24 September 2018

LOCAL ACTIONS TO ENSURE aTIV IS OFFERED TO INDIVIDUALS AGED 65 YEARS AND OVER

The manufacturer of aTIV, Seqirus has confirmed sufficient availability of the vaccine to meet anticipated demand and has communicated with GP practices and community pharmacies the exact date and volume of each of their deliveries.

Some practices and community pharmacies did not meet the deadline for ordering and where that is the case – or where demand exceeds supply in an individual surgery or pharmacy – action should be taken at local level as set out in this briefing, to ensure the stock of vaccine is distributed to meet demand.

Where practices have ordered sufficient aTIV for their local population aged 65 years and over, they should follow the previously published guidance in delivering the programme.

The Medicines and Healthcare Products Regulatory Agency (MHRA) has a role in regulating medicines supply. Normally, medication can only be passed between providers where a wholesaler licence exists, however the MHRA has confirmed that with regards to the adjuvanted trivalent flu vaccine (aTIV) recommended for those 65 years and over, it would not prevent supply under the given circumstances of "in short supply" or "no supply" available provided that:

- the surgery that is holding the excess stock can give an assurance that the vaccine has been held properly in the correct temperature controlled conditions;
- confirmed record keeping of temperature monitoring is available;
- the surgery that requests the aTIV is able to verify the assurances given;
- the vaccine can be transported appropriately under the right conditions.

Community Pharmacies are already able to transfer medicines to other healthcare providers without a wholesalers licence under specific circumstances, and should refer to the relevant guidance at https://www.gov.uk/government/publications/repeal-of-wholesale-dealer-licence-exemption-for-pharmacists.

This means that clinicians are able, and expected, to work with other surgeries and pharmacies to safely move vaccine stock between locations, in order to ensure that the sufficient stock of vaccine is distributed to reflect actual demand.

Guidance on this is available in Chapter 3 of the Green Book 'Storage, distribution and disposal of vaccines' https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3. Providers intending to supply vaccine or receive vaccine should follow the recommendations in this.

Local Actions

1. NHS England regional teams, together with local public health commissioning teams (including SITs), will be working with CCGs to co-ordinate the local plans for aTIV delivery if gaps in availability are identified. NHS England regional teams should have a named lead for seasonal flu vaccination.

2. All general practices should have already assessed that their confirmed total vaccine order is sufficient for patients likely to attend the surgery for vaccination. This will take into account historical attendance numbers, expected uptake rate and consideration of the numbers of patients likely to attend a community pharmacy for immunisation. This information by now should have been provided to their CCGs to feed into the local assessment of aTIV availability.

3. CCGs should have a named lead for seasonal flu and be planning to support practices by working with NHS England, the Local Medical Committee (LMC), community pharmacy and the Local Pharmaceutical Committee (LPC) to ensure those age 65 and over have access to aTIV. We are aware that this work has already started.

4. Where a practice has not been able to order aTIV, they should work closely with local pharmacies to direct patients to a locally available source of aTIV. In this circumstance, issuing prescriptions for aTIV would not be appropriate.

5. Where a pharmacy has not ordered aTIV then they should direct patients to a locally available source of aTIV at their registered practice or another local pharmacy. CCGs and NHS England local teams will be working with other local stakeholders to support practice planning.

6. Note: In 2018/19 pharmacies do not have to sign up for the community pharmacy seasonal flu advanced service prior to delivery so the weekly sign up lists will not be available from the NHSBSA as in previous seasons. NHS England local teams/and or LPCs should be able to access information on the majority of pharmacies delivering the service through the PharmOutcomes or Sonar web-based systems used in the flu programme.

7. Although aTIV is the preferred vaccine, QIV can be offered in exceptional circumstances as it will likely still give important protection.

8. Only if there is no accessible supply, and no further supplies are expected, would it be clinically appropriate to offer QIV to eligible patients. This decision would be made on a case-by-case basis taking into account an individual's personal circumstances. The reason for electing to give QIV should be documented by the clinician.

    - People 65 years and over should not be offered QIV other than in exceptional circumstances. If aTIV is not available then the first step is to signpost them to another provider where it is available. In the event that aTIV is not available, and is highly unlikely to become available, QIV may then be offered as a second line option.

    - Although this is unlikely to be the case, if eventual demand nationally exceeds anticipated supply practices and pharmacies should offer QIV to any remaining eligible patients over 65 years of age.

9. If offering QIV to individuals who would benefit from the more appropriate aTIV, when gaining consent for immunisation, practitioners should ensure they inform the individual the vaccine is not one nationally recommended for them. Healthcare practitioners should ensure they explain to the individual the possible lower efficacy of the vaccine being offered to them, why it is being offered instead of the recommended vaccine and why it may still offer protection against seasonal flu, or attenuate the progression of the infection should they get it. The discussion should be documented in the individual's records.

10. Summary of roles

NHS England Regional directors	Oversight and assurance of regional response and CCG/practice plans for aTIV delivery.
NHS England regional lead	Co-ordination of response at regional level. Liaising with NHS England local public health commissioning teams. Liaising with CCGs.
Local PH Commissioning teams; Heads of Public Health and Screening and Immunisation teams)	Liaise with NHS England regional leads. Work with CCGs, LPCs, LMCs and other local stakeholders. Support development of local practice plans.
CCGs	Should have a named lead for seasonal flu. Work with local practices to identify any gaps in supply and offer support. Ensure practices have appropriate plans in place. Participate in local planning with NHSE, LPC and LMC.

BACKGROUND AND PREVIOUSLY PUBLISHED GUIDANCE

11. Following advice from the Joint Committee on Immunisation and Vaccination (JCVI) and Public Health England (PHE), NHS England wrote to GPs, CCGs, community pharmacies and NHS trusts in February 2018 stating the recommended flu vaccines that should be used in 2018-19:

    - aTIV is the recommended vaccine for people 65 years and over
    - Quadrivalent inactivated influenza vaccine (QIV) is the recommended vaccine for adults under 65 in at risk groups and healthcare workers
    - Non-adjuvanted TIV is not recommended for any group.

    https://www.england.nhs.uk/publication/vaccine-ordering-for-2018-19-influenza-season-letters/

12. Seasonal flu vaccination is available to people aged 65 years and over from their registered GP practice or at a community pharmacy providing the community pharmacy seasonal flu advanced service. Following an extended ordering period GP and community pharmacy orders for aTIV in England total ~7.8 m doses (in 2017/18 around 7.4m doses were given to this age group achieving 72.6% uptake against the target of 75%). Ordering closed in May 2018 and Seqirus, the supplier, has confirmed that they are able to provide sufficient quantities of the vaccine to meet anticipated take-up.

13. For 2018-19 the aTIV deliveries to all practices and pharmacies will be phased; 40%/20%/40% over September/October/early November. This phasing mirrors the uptake pattern of the vaccine in 2017/18. NHS England issued a Q&A about staged delivery to practices and pharmacies in March confirming this and advising them to begin plans for vaccination clinics based on this schedule.

14. NHS England issued a letter and guidance in August 2018 to practices and pharmacies to support them in managing programme delivery and prioritising the available supplies to: i) those age 75 years and over; ii) care home residents; and iii) those in clinical risk groups 65-74 years of age being higher priority.

    https://www.england.nhs.uk/publication/flu-vaccination-programme-delivery-guidance-2018-19/

15. In addition Public Health England has published two key supporting documents
    a. **Summary of data to support the choice of influenza vaccination for adults in primary care (PHE January 2018)**

       https://www.gov.uk/government/publications/flu-vaccination-supporting-data-for-adult-vaccines/summary-of-data-to-support-the-choice-of-influenza-vaccination-for-adults-in-primary-care

b. Inactivated influenza vaccine: information for healthcare practitioners (PHE August 2018)

Gives healthcare professionals detailed information about inactivated flu vaccines including *'Exceptional use of QIV and non-adjuvanted TIV outside of national recommendations for the 2018/19 influenza season'* (p10.) This clarifies when aTIV would be considered 'unobtainable' and other vaccines could be considered and the consent issues associated with this.

https://www.gov.uk/government/publications/inactivated-influenza-vaccine-information-for-healthcare-practitioners