

## DHSC Guidance for NHS Providers on accessing DHSC centrally supplied flu vaccines

#### 23 October 2020

#### Summary

As you will be aware, the Department of Health and Social Care (DHSC) has announced its intention to run the largest flu programme ever in the 2020/2021 flu season. Part of this includes a drive to increase uptake in existing cohorts eligible for a free vaccine under the NHS programme, and also expansion to new groups. In order to support the expanded vaccination programme, the Department has secured an additional supply of influenza vaccines, which arrive later in the season to top up local supplies once they run low. We are now able to confirm the process by which NHS Providers will be able to access this additional stock. NHS Providers are defined by those providing NHS services under the NHS Standard Contract. For the avoidance of doubt, this stock is only available for frontline healthcare workers, commissioned to deliver NHS clinical services under that contract. The stock may also be used to vaccinate eligible cohorts only when contracted to do so. This includes NHS Trusts and independent providers who fall under these conditions.

GP guidance has been released separately and a pre-set proportion of this additional stock will also be made available to community pharmacy, with the arrangements for them to order against this stock detailed separately.

Please note that the stock arrives during October, November and December. Expected first delivery dates are included within the detailed guidance below.

In designing the process for accessing additional stock, consideration has been given to how NHS Providers currently source and administer flu vaccinations. It has been purposefully designed to limit the impact on business as usual vaccinations and supply chains. We also have a responsibility to balance this with the need to protect and mitigate risks of unintended use, as this is a taxpayer funded programme, whilst acknowledging the exceptional circumstances that has warranted the programme's expansion.

NHS Providers will be provided the add vaccines free of charge to vaccinate frontline staff and patients eligible for a free vaccine under the NHS programme where the provider has been specifically commissioned to do so. All frontline health and social care workers should receive a vaccination this season which should - in the case of NHS Providers - be provided and funded by their employer, in order to meet their responsibility to protect their staff and patients and ensure the overall safe running of services.

Some staff may be eligible for a free NHS vaccine, which they can access at their registered GP practice or a community pharmacy, if they fall within one of the eligible cohorts set out in the Updated Annual Flu Letter. Thus, it is expected that all NHS Providers should vaccinate frontline healthcare workers with locally procured stock first before accessing additional stock.



The additional vaccine supply may also be used to vaccinate eligible patients under the maternity and at-risk cohorts service specification. In these cases the NHSEI Public Health Commissioner and NHS providers will need to agree the impact of any additional activity on agreed payment mechanisms taking into account whether providers have utilised free of charge vaccines.

The majority of the additional stock will arrive from November onwards, and NHS Providers will be able to access this only once their own local stocks are depleted. The MHRA has granted a dispensation to allow movement of vaccines locally between other NHS provider organisations and we would encourage you to work with regional NHSEI Public Health Commissioning team to understand what stock is available locally before accessing the national additional supply. You may also wish to liaise with other providers within the local system. The additional supply should only be used when there are no other alternative options to accessing more vaccines.

As part of the process for NHS providers to access free additional flu vaccines, you will be required to capture and record details of the vaccinations given to aid the management of the national flu programme. As you will be aware, the method to record the vaccine event is to use the National Immunisation Vaccine System (NIVS) digital solution. NIVS is being used in multiple service provider settings to capture flu vaccination event information. This system is the requisite submission tool for flu vaccination data for all healthcare workers and also where NHS Providers are administering the vaccine in other settings including under 65 clinical at risk groups (e.g. maternity departments or through other in and outpatients setting for clinical at-risk cohorts). Communication to NHS providers on the use of the NIVS system was issued on 14<sup>th</sup> October by NHSEI. If you have any questions regarding the system or require further information, please contact agem.nivs@nhs.net.

Please note as in previous seasons, the routine monthly PHE data collection for healthcare workers will operate using the ImmForm website. Data reported through ImmForm continues in parallel and remain the official statistics for the Influenza immunisation programme.

#### How to order additional stock

This guidance covers NHS Providers in England. Guidance for GP practices has been issued separately and community pharmacy will be published shortly.

- Assess if there is a need for further flu vaccines by assessing current and expected uptake rates in eligible cohorts (taking into account booked clinics) compared with your current vaccine supply (including ensuring that you have received all of the vaccines you have ordered from suppliers for each eligible cohort). You will not be able to use additional stock until all of your other orders have been received and used.
- 2. Providers may order sufficient vaccines to vaccinate frontline healthcare staff if you have not managed to satisfy this requirement using stock ordered earlier in the season In addition, some providers are also commissioned to vaccinate patients in eligible cohorts through maternity services and other in and outpatient settings for the clinical at-risk cohorts. Therefore, NHS Providers may also order vaccines for the approved cohorts they are commissioned to vaccinate
- **3.** Keep in contact with your Regional NHSEI Public Health Commissioning Team on your levels of stock and any additional stock you may need as they may be able to advise of surplus



stock held locally by another provider that you can access. You may also wish to liaise with other NHS providers within your local area to confirm if they have any surplus stock you can access.

- 4. Order additional vaccines only when you have allocated all of your locally procured stock for example you have confirmed you cannot take any bookings for patients or frontline healthcare workers vaccination clinics. You should only be using additional stock to vaccinate patients or frontline healthcare workers once you have used and/or committed all of your locally procured stock to booked appointments those cohorts. Additional stock is not to be used to manage temporary shortages for a particular cohort, e.g. to tide you over until you receive a further delivery of local stock from suppliers.
- 5. Information on all of the manufacturers that additional stock has been ordered from is included below in Table 1, however we are directing NHS Providers to particular manufacturers in the first instance. If you have a pending order with Sanofi Pasteur, distribution channels for this are being confirmed and you will be contacted about this. If you have not placed an additional order with a manufacturer, or normally purchase flu vaccines through a wholesaler, please in the first instance order from GSK for quadrivalent influenza vaccine (QIVe), and Seqirus for adjuvanted trivalent influenza vaccine (aTIV).
- 6. You may need to register an account with the relevant manufacturer of additional stock, for information accounts may take a week or more to set up, and you should also familiarise yourself with the ordering process for each supplier. DHSC may provide periodic updates on central stock levels available from suppliers to the Regional NHSEI Public Health Commissioning teams, so you should keep in regular contact with your regional team.
- **7.** In order to access additional stock, NHS Providers will be required to sign a self-certification declarations to manufacturers before they can access stock.
- **8.** NHS Providers will be required by each manufacturer for every order they make to self-certify that:
  - a. You have allocated all of the locally procured flu vaccines and any additional flu vaccines you have previously ordered, including any vaccines yet to be delivered, for the cohort(s) that you require additional vaccine for.
  - b. You agree not to return any of your local stock order for those cohort(s) to manufacturers, as additional stock is only to be used after all of your local stock for a particular cohort has been exhausted.
  - c. You will only use additional stock to vaccinate frontline healthcare workers and patients who you have contracted services to vaccinate. This will include those frontline healthcare workers and patients who fall into eligible groups included in the national flu immunisation programme, as set out in <u>Appendix A of The national flu immunisation programme 2020 to 2021- update</u> and whom you are commissioned to vaccinate.
  - d. If applicable, you will claim the correct fees for additional flu vaccines.



- **9.** NHS Providers should only order enough vaccines to cover your expected demand as you will not be able to return unused additional flu vaccines. Maximum order limits have been put in place to ensure all areas of England have access to additional vaccine supplies and to prevent stockpiling. Please note the minimum/maximum order sizes and the delivery times advised by the relevant manufacturer. DHSC will monitor orders as the season progresses and may update ordering limits to manage supply. Ordering too frequently may limit the availability of delivery slots and may require DHSC to alter the ordering policy to ensure all appropriate providers have access to stock.
- **10.** If an NHS Provider has an ordering requirement exceeding the parameters set out in Table 1 below, the Provider should contact their NHSEI Regional Public Health Commissioning Team.
- **11.** As stock and delivery slots are limited, orders and stock levels will be closely monitored by DHSC to understand local demand, prevent supply issues and ensure the appropriate use of central stock.
- **12.** NHS Providers should have systems in place to store and administer locally and additional supplied stock in such a way to support accurate record keeping and financial claims.
- **13.** You will not be able to return any unused stock to manufacturers. Towards the end of the season, if you find yourself with an excess of additional stock that you will not use we advise you to contact your Regional NHSEI Public Health Commissioning Team so they can support the re-distribution of the stock to another local provider.
- 14. In the very unlikely circumstance that an NHS Provider finds itself with a small amount of unused additional stock and only after notifying your regional NHSEI Public Health Commissioning Team and making every effort to redistribute the stock, providers will be required to dispose of any unused additional stock themselves. Disposal must be conducted in line with standard procedures. Providers should keep clear records as to the amount, type of vaccine(s) and batch numbers redistributed or disposed of.
- **15.** NHS providers are prohibited from supplying additional supplied stock to a third party in exchange for payment.



Table 1 – Vaccines available from each manufacturer, timescales and minimum order quantities. Expected first delivery dates are indicative as these are not confirmed and may change

Manufacturer	Product	Vaccine type	Ovalbumin content micrograms/dose	Expected first deliveries to DHSC
GlaxoSmithKli ne (GSK)	Fluarix Tetra	QIVe (standard egg- grown quadrivalent influenza vaccine), split virion, inactivated	Equal to or less than 0.05 micrograms per 0.5 ml dose	w/c 9 <sup>th</sup> Nov
Sanofi	Quadrivalent Influenza vaccine	QIVe (standard egg- grown quadrivalent influenza vaccine), split virion, inactivated	Equal to or less than 0.05 micrograms per 0.5 ml dose	w/c 16 <sup>th</sup> Nov
Seqirus	Adjuvanted Trivalent Influenza Vaccine	aTIV (egg-grown trivalent influenza vaccine), surface antigen, inactivated, adjuvanted with MF59C.1	Equal to or less than 0.2 micrograms per 0.5 ml dose	w/c 19 <sup>th</sup> Oct

### Department of Health & Social Care Appendix A – Manufacturer ordering processes

#### GlaxoSmithKline

Manufacturer	Product	Minimum order	Maximum order	Delivery time
GlaxoSmithKline	QIVe	200*	5000	Orders placed by 12pm on Thursday will be delivered the following week (Monday-Friday).

#### \*Orders should be in multiples of 200

#### **Registration and Ordering**

Orders for Fluarix Tetra (influenza vaccine (split virion, inactivated)) can be placed online at www.ukfluportal.gsk.com.

Deliveries will commence week of 16<sup>th</sup> November 2020.

Before proceeding with an order, providers will be required to register online on the GSK Flu Vaccine Ordering Portal.

Alternatively, providers can log in to the GSK Flu Vaccine Ordering Portal using their Vaccines.co.uk email address and password, if they already have an account.

Account verification can take up to 10 working days if additional information is required, so we encourage registration as early as possible to avoid delays.

To help verify accounts as quickly as possible, GSK will require a Professional number e.g. GMC/NMC/GPhC.

#### Contact

Email: uk.flu@gsk.com



Manufacturer	Product	Minimum order	Maximum order
Sanofi	QIVe	100	5000
Pasteur			

#### Sanofi Pasteur

Distribution channels are being confirmed and new orders are currently not being taken. If you have a pre-existing eligible pre-order details on confirming this will follow.



#### Seqirus

Adjuvanted Trivalent Influenza Vaccine (aTIV)

Manufacturer	Product	Minimum order	Maximum order	Delivery time
Seqirus	aTIV	20	150	Within 7 business days of
				ordering, providing you
				already hold an account
				with the supplier

Customers email <u>DHSCvaccines@seqirus.com</u> to request an order form and then send back the completed order form to the same email address.

Seqirus process orders and deliver within 7 business days of ordering.

A Zero value invoice (PDF) will be generated to the DHSC account after shipment, and DHSC will receive conformation of the order.

Seqirus Customer Service – 0845 745 1500

### Department of Health & Social Care Appendix B – Frequently Asked Questions

#### 1. What stock is available?

Enough stock is available for eligible groups. The department has worked with all manufacturers of adult flu vaccines to increase supply for use in England. There are a range of products available to cover eligible cohorts. There are ordering limits in place for each product, as detailed in Table 1.

#### 2. Why are there limits in place on the stock that I can order?

Limits have been put in place to ensure that all areas of England are able to access the stock and to prevent stockpiling. An NHS Provider should make an accurate assessment, once local supplies have been exhausted, of how many doses of additional vaccines it needs for each eligible cohort. NHS Providers can make multiple orders for additional stock, however it is recommended that providers should only place one order at a time and it should be noted that delivery slots are limited. Delivery slots will be prioritized so please consider your ordering requirements to complete your vaccination, however you will be permitted to submit additional orders after your initial order. Ordering too frequently may limit the availability of delivery slots and the DHSC may update the ordering policy to ensure all providers have access to stock.

DHSC has worked with manufacturers to provide sensible minimum order volumes but these need to be balanced with the number of delivery slots available.

#### 3. Who can be immunised with vaccine from additional stock?

In line with the aim of the national flu immunisation programme, the additional stock can be used to vaccinate frontline healthcare workers and patients for whom you have a contract in place to vaccinate. This will include those frontline healthcare workers and patients who fall into eligible groups included in the national flu immunisation programme, as set out in <u>Appendix A of The national flu immunisation programme 2020 to 2021- update</u> and for whom you have been specifically commissioned to vaccinate.

### 4. Can I use additional stock to vaccinate frontline healthcare volunteer workers if I have run out of my local stock?

You should vaccinate all frontline health care workers working in your organisation as appropriate, this will include those directly employed, those who are sub-contracted/on honorary contracts (e.g. bank and agency staff) and those who are working unpaid unless you are assured that they have been vaccinated elsewhere this season.

#### 5. What are the requirements for recording the use of vaccines?

As part of the process for accessing free additional vaccines, you will be required to capture and record details of the vaccinations to aid the management of the national flu programme. As you will be aware, the NIVS digital solution is being used in multiple settings to capture flu vaccination information. The system is the requisite submission tool for flu vaccination data for all healthcare workers and also where NHS Providers are administering the vaccine in other settings (e.g. maternity departments or through other in and outpatients setting for clinical at-risk cohorts). Further communications on the system will be sent shortly which will cover secondary care settings and healthcare workers. If you have any questions regarding the system or require further information, please contact <u>agem.nivs@nhs.net</u>.



Please note as in previous seasons, the routine monthly PHE data collection for healthcare workers will operate using the ImmForm website. Data reported through ImmForm continues in parallel and remain the official statistics for the Influenza immunisation programme.

If an NHS Provider finds itself with a small amount of unused additional stock and only after notifying your regional NHSEI Public Health Commissioning Team and making every effort to redistribute the stock, providers will be required to dispose of any unused additional stock themselves. Disposal should be conducted in line with standard procedures. Providers should keep clear records as to the amount, type of vaccine(s) and batch numbers redistributed or disposed of. NHS providers are also prohibited from supplying additional supplied stock to a third party in exchange for payment.

# 6. I have currently used up all of my stock of aTIV, but am expecting another delivery of aTIV from my normal order, can I order some from the additional stock so I don't have a temporary shortage?

No you cannot, additional stock can only be used once an NHS Provider's locally procured stock supplies have been exhausted/fully allocated and cannot be used to plug temporary shortfalls in the availability of locally procured vaccines.

### 7. Can I use additional stock to vaccinate Social Care Workers who are eligible for a free vaccine?

Social care staff can obtain the flu vaccine for free from their GP or at a community pharmacy, you should refer to guidance set out here: <u>https://www.gov.uk/government/publications/flu-immunisation-for-social-care-staff</u>

# 8. Can I order vaccine if I have run out of vaccine for one cohort but not another? For example running out of QIVe but not aTIV, and I am not expecting to receive any more QIVe?

Yes, you can. If you have run out of a vaccine for a particular cohort you can access the additional stock even if you have stock or further deliveries pending of another vaccine for use on a <u>separate</u> <u>cohort</u>. For example if you have run out of QIVe to vaccinate at frontline healthcare workers aged 18-64 and <u>aren't going to receive any more</u>, but still have a local order of aTIV for your frontline healthcare workers aged over 65 yet to arrive, you can place an order for QIVe from the additional stock.



### 9. Which brand of vaccine are available? Are they suitable for all ages and clinical needs?

Vaccines have been ordered by DHSC from a number of manufacturers. This was done to reduce the likelihood of the additional stock being seriously affected should a problem occur with a single manufacturer.

Health professionals accessing additional stock will have a choice of flu vaccines and should order the vaccine(s) best suited to their patient population in line with JCVI guidance as set out in the National flu immunisation programme 2020 to 2021 letter and in the Green Book on suitability of each product for different age groups, and clinical needs such as severe egg allergy (anaphylaxis). More detailed information is available from the manufacturers' summaries of product characteristics.

#### (www.medicines.org.uk).

In the first instance

#### 10. Can multiple orders for additional stock be placed at the same time?

We ask NHS Providers to order stock only when they are sure they will be able to use it. Ordering too much stock may lead to shortages for other providers. NHS Providers will be able to make additional orders if they run out from of their additional stock order. Ordering too frequently may limit the availability of delivery slots and may require DHSC to alter the ordering policy to ensure all providers have access to stock.

DHSC are directing NHS Providers to particular manufacturers in the first instance. If you have a pending order with Sanofi Pasteur, you should contact them to confirm this. If you have not placed an additional order with a manufacturer, or normally purchase flu vaccines through a wholesaler, please in the first instance order from GSK for QIVe, and Seqirus for aTIV.

#### 11. Can I order additional stock from more than one manufacturer?

Yes, if it is for different products, however we recommend NHS Providers only order stock they are sure they are able to use. Ordering too much stock may lead to shortages for other providers. NHS Providers will be able to make additional orders if they run out from their first additional stock orders. Delivery slots will be prioritized so please consider your ordering requirements to complete your vaccination. Ordering too frequently may limit the availability of delivery slots and the DHSC may update the ordering policy to ensure all providers have access to stock.

DHSC are directing NHS Providers to particular manufacturers in the first instance. If you have a pending order with Sanofi Pasteur, you should contact them to confirm this. If you have not placed an additional order with a manufacturer, or normally purchase flu vaccines through a wholesaler, please in the first instance order from GSK for QIVe, and Seqirus for aTIV.

#### 12. Do I have to pay for additional stock?

No, DHSC stock has been paid for by the department and will be provided to NHS Providers free of charge. Commissioners and NHS Providers will need to agree the impact of any additional activity on block payments taking into account whether providers have had to pay for additional vaccine.

#### 13. How will payments for vaccinations administered work?

The additional vaccine supply may also be used to vaccinate eligible patients where NHS Providers are commissioned to do so. In these cases the NHSEI Public Health Commissioner and NHS providers



will need to agree the impact of any additional activity on agreed payment mechanisms taking into account whether providers have had to pay for additional vaccine.

#### 14. What do I do with unused stock at the end of the season?

If you have accessed additional stock you should have exhausted all of your local stock first. It is therefore not anticipated that providers will have any unused local stock if you have accessed additional stock. Manufacturers will also require you to confirm as part of the declaration process for ordering additional stock that you will not return any local stock. In light of high demand for flu vaccine this season and the significant expansion of the programme – along with the ability to redistribute stock locally – it is not expected that any additional stock will go unused. However, in the very unlikely circumstance that an NHS Provider finds itself with a small amount of unused additional stock and only after notifying your regional NHSEI Public Health Commissioning Team and making every effort to redistribute the stock, providers will be required to dispose of any unused additional stock themselves. Disposal must be conducted in line with standard procedures. Providers should keep clear records as to the amount, type of vaccine(s) and batch numbers redistributed or disposed of. NHS providers are prohibited from supplying DHSC supplied stock to a third party in exchange for payment.

## 15. What if, even after accessing additional stock, I still have insufficient stock to meet demand?

You should speak to your Regional NHSEI Public Health Commissioning Teams to determine if any other providers have surplus stock that you can access. In addition, for eligible patients outside of your frontline healthcare worker commitments, you could re-direct patients to their registered GP or local community pharmacies (aged over 18 years only) if they have stock available.

## 16. Will I easily be able to distinguish between locally procured stock and centrally procured stock so I can ensure I claim the correct payment?

In most (but not all cases), the additional centrally procured stock will have different batch numbers to locally procured stock. NHS Providers should put in place arrangements to clearly label and if possible, store additional stock separately to locally procured stock to ensure NHS block payment adjustments for additional activity can be justified. NHS Providers should be accessing additional stock only when they are no longer expecting to receive any more locally procured stock for that particular vaccine.

#### Further information

Throughout the season, information and updates will be shared with Regional NHSEI Public Health Commissioning Teams.

If you have any further queries, please contact england.fluops@nhs.net.