

ICARS Newsletter

Immunisation Clinical Advice & Response Service

NHS



Issue 88: 16th May 2022

PLEASE SHARE THIS NEWSLETTERS WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

For any COVID-19 vaccination related queries, or to escalate an incident, please contact ICARS at england.swicars@nhs.net. Please note that this service operates 9am-5pm Monday to Friday

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1. NEW: AstraZeneca Vaxzevria®

1a) C19 Vaccs: Conditional Marketing Authorisation for Vaxzevria® COVID-19 vaccine manufactured by AstraZeneca - impact of granting a Conditional Marketing Authorisation for Vaxzevria® COVID-19 vaccine

Previously AstraZeneca was issued a temporary authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) under Regulation 174 (R174) of the Human Medicines Regulations 2021 to permit the supply of batches of COVID-19 Vaccine AstraZeneca (ChAdOx1 S [recombinant]) (AZ). AstraZeneca has now been granted a Conditional Marketing Authorisation (CMA) by the MHRA for their COVID-19 vaccine, branded as Vaxzevria®.

It is important to note that there are no quality, safety or efficacy implications from the change in licensing status of the new licensed stock. There are also no changes to the vaccine's characteristics or its administration and handling requirements.

The Summary of Product Characteristics (SPC) for Vaxzevria® is available [here](#).

The first deliveries of Vaxzevria® to vaccination sites are currently planned to begin in the week commencing 16 May. The last deliveries of the R174 AZ product will be made on Friday 13 May 2022 to vaccination sites. All remaining stocks of the Reg174 product have a 31 May expiry date.

Although there are no vaccine handling differences between Vaxzevria® and the R174 product, there are legal differences between the two. In order to minimise the legal and clinical risk of inadvertently using the wrong vaccine, vaccination sites should avoid holding both stocks in refrigerators where possible. If this is not possible, vaccination sites must maintain adequate segregation of the two products and prioritise the use of R174 AZ up until the 31 May but ensuring it is not used past its expiry date.

Once the R174 product reaches its expiry point, vaccination sites should dispose of any remaining unused vials locally following their standard operating procedure. Please ensure wastage is accurately recorded on Site Stock Manager and that a zero stocktake is completed for all R174 stock.

The operational implications for the management of the Vaxzevria® COVID-19 vaccine are listed below and you are asked to take appropriate steps to make relevant colleagues aware of these changes. These changes apply specifically to Vaxzevria® branded stock.

Topic	Changes relating to transition to CMA for Vaxzevria® COVID-19 vaccine
Timescale – estimated first likely delivery to NHS frontline	Week commencing 16 May 2022
Training for vaccinators	No need for training to be repeated based on this change. For those that have not completed training, updated training is available from the UKHSA at the e-learning for healthcare website here
National Protocols and/or Patient Group Directions	New Patient Group Directions and/or National Protocol for Vaxzevria® are available here
Specialist Pharmacy Service (SPS) Standard Operating Procedures (SOP)	There is no change to the handling of this product. SPS SOPs are available here

Point of Care (POC) and Foundry Ordering Platform Systems	The Vaxzevria® name has been added to the Ordering Platform and will shortly be added to all POC systems. Until the POC systems have been updated to enable Vaxzevria® to be selected, sites are asked to add a note on the POC that Vaxzevria® was administered and not R174 AZ.
Summary of Product Characteristics (SPC)/Patient Information Leaflet (PIL)	Minor text differences. New Vaxzevria® Patient Information leaflet (PIL) supplied with vaccine and must be issued to patients given Vaxzevria® vaccine. The SPC is available here
Artwork on vaccine box	Vial and carton label changes including name, colour scheme and branding logo. Images of the new artwork can be found below
3 rd dose timing	Registered timing for providing booster dose has been changed from after 8 weeks for R174 to after 6 months for Vaxzevria® NHSE practices are unchanged and will continue to follow JVCI guidance.

To ensure the vaccine is safe and effective at the point of use, it is extremely important that the conditions of the Marketing Authorisation, and the SPS Standard Operating Procedures for handling are adhered to at all points in delivery of your vaccination service.

1b) PGD and National Protocol for Vaxzevria V01.00 has been published

The Patient Group Direction (PGD) and National Protocol for Vaxzevria V01.00 have now been published and can be accessed via: [https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-\(pgds\)](https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)).

1c) Example of Vaxzevria® Carton and Vial:



2. NEW: Permanent removal of the 15-minute observation period following COVID-19 vaccination

The 15-minute observation period following vaccination with Comirnaty 30 micrograms/dose concentrate for Adults and Adolescents and Spikevax COVID-19 vaccines has been removed

for individuals aged 12 years and over who have no history of a severe allergic reaction (as outlined in the [Greenbook advice](#)).

This follows careful review of the safety data by the MHRA and advice from the government's independent Commission on Human Medicines. **A temporary suspension of the 15-minute observation period for children aged 5-11 years remains in place and this will be reviewed on a regular basis.**

This information is formalised in the Details section of the MHRA pages for [Spikevax](#) and [Comirnaty 30 micrograms/dose concentrate for Adults and Adolescents](#).

A 15-minute observation period is also recommended for those individuals who had non-allergic reactions such as vasovagal episodes, non-urticarial skin reaction or non-specific symptoms following previous vaccine doses.

Following vaccination with any of the COVID-19 vaccines, all individuals should be observed for any immediate reactions whilst they are receiving information and, where applicable, leaving the site. If at any point during this time an individual appears unwell or there are concerns about potential adverse effects, they should be advised to remain on site for a period of observation and monitoring.

In some settings, such as when vaccinating individuals who are housebound, it is advised that a responsible adult be present with the individual for a period of at least 15 minutes. This may be a member of the vaccinating team, a relative, carer or friend. Vaccinating teams may wish to advise individuals of this prior to the appointment so that they may be able to identify a responsible adult in advance.

Individuals should be made aware of the signs and symptoms of anaphylaxis and the information leaflet 'Waiting after your COVID-19 vaccination' can be used alongside verbal counselling to reiterate these points. Individuals should be informed about how to access immediate healthcare advice in the event of displaying symptoms.

Vaccination sites should retain an observation and monitoring area. The reporting of adverse reactions, including anaphylaxis, via the Yellow Card Scheme remains essential in order that the MHRA can continue to monitor the situation closely.

Guidance was issued on the 16 December on the **temporary** suspension of the 15-minute observation period available [here](#).

3. NEW: Learning Disability & consent

There is an evergreen offer for people with a learning disability and/or autism to receive any of the first 3 doses of the vaccination that have not yet been received. For those who lack capacity to make a decision around receipt of the vaccinations, professionals are advised to make use of the Mental Capacity Act and Best Interest approach to support decision making on an individual basis.

There have been a number of cases where vaccination agreement could not be reached by the family and these cases have resulted in a Court of Protection decision.

Whilst on occasion this may be an appropriate course of action, the Court of Protection processes are only required where an agreement around treatment (vaccination) cannot be reached in a person's best interest. In all other cases a Best Interest decision can be reached and followed.

NHS England and NHS Improvement Safeguarding Team London Region have produced a [flow chart](#) which can be used and shared with colleagues.

Additional information can be found here:

[Consent within the Vaccination Process](#)
[Mental Capacity Act](#)

4. NEW: Spikevax® (Moderna) calendars for Community Pharmacy-led LVS

In the coming week, Spikevax® (Moderna) calendars will be added in Q-Flow as a new service line to all those community pharmacy-led LVS sites who do not currently have one. You should now prioritise this vaccine usage. The calendar can be managed in the same as your other vaccine calendars and a reminder of the guidance for creating appointments can be found here: [Create appointment availability - NHS Digital](#).

Sites must continue to ensure capacity remains available to support young people aged 16 to 17 years old who **must only receive the Comirnaty® (30 microgram/dose) vaccine**.

Further guidance for managing calendars can be found [here](#).

5. UPDATE: Patient Information Leaflet (PIL) for Comirnaty® 10 microgram/dose Concentrate for Children 5-11 years

Current deliveries of the Comirnaty® 10 microgram/dose Concentrate for Children 5-11 years take the form of packs designed for the European Union (EU) and are not specific to the UK. Each original pack contains one EU PIL. These EU PILs must not be given to children or their responsible adult, and vaccination teams are requested to discard these at point of use. Sites will continue to receive packs of UK PILs with each vaccine delivery and each child who receives a Comirnaty® 10 microgram/dose vaccination should continue to receive one of these UK PILs as per the standard process.

Further information can be found in the communication dated 27th April from the [Supply and Delivery Hub](#).

6. UPDATE: Infection Control measures in social care settings

The guidance for infection prevention and control in adult social care settings in England has been revised and can be found [here](#).

This guidance was updated 3 May 2022 and should be read alongside the [infection prevention and control \(IPC\) resource for adult social care](#). This supplement should also be read with the [adult social care testing guidance](#), which details the testing regimes for all staff, as well as any resident and outbreak testing where applicable.

7. REMINDER: Site calendar availability for the June bank holiday on Q-Flow

This is a reminder to Site Managers to make sure availability in Q-Flow calendars reflect closures that are planned across the bank holidays on 2 - 3 June. Q-Flow does not automatically block out bank holidays, therefore it is particularly important to check any availability that is set to 'repeat' over that period. If the site will be closed, you will need to amend the availability. If you have any questions or need advice the team are running drop in sessions 13:30-14:00 on Mondays, Wednesdays and Fridays - [Click here for NBS Drop In Sessions](#).

8. REMINDER: New stock take compliance process for vaccine orders went live this Monday 9 May

From Monday 9 May 2022, sites that have not completed a 7 day stock take will be notified that their order cannot be placed until a new stock take has been completed by a pop-up box on the system. Once a stock take has been completed, sites will be able to go back onto the Ordering Platform and raise their order again. **Please note, it can take a maximum of 2 hours and a minimum of 45 minutes for a new stock take to be registered by the system and allow an order to proceed.** The system will make allowances for new sites and sites that might have paused vaccinations and had no deliveries for a while.

Sites that are not already conducting a weekly stock take are requested to commence these, to avoid this new process impacting them.

FAQs are available on NHS Futures [here](#) to support sites with any questions they may about this process.

9. REMINDER: Combined Needles and Syringes On/Off Logic

Due to the variations in the pack sizes of the combined needles and syringes (CNS) currently utilized in Vaccine Deployment Programme, compared to the number of doses per box of vaccine, it is sometimes necessary to provide an oversupply of CNS.

To ensure we do not keep oversupplying CNS to sites, there is a logic built into the Foundry Ordering Platform system that checks when a site places an order to see whether it has received an oversupply of CNS in the past 90 days. If it has, then the system automatically reduces or removes the CNS from future orders until the oversupply equals or nearly equals the quantity of vaccine doses it has received.

For example:

A site orders 270 doses of Comirnaty® (30 microgram/dose) and receives 300 administration CNS since (as these come in packs of 100 needles). Site is oversupplied by 30 CNS.

The site then orders 270 doses of Comirnaty® (30 microgram/dose) each week for the next 3 weeks, receiving a total of 1,080 doses of vaccine and 1,200 administration CNS. Resulting an oversupply of 120 CNS across the 4-week period.

To mitigate this oversupply, the next order the site places for Comirnaty® (30 microgram/dose) would have its order of administration CNS reduced by 100, so that the total oversupply of the previous 4-weeks is reduced to 20 units.

This logic also applies to the Comirnaty® (30 microgram/dose) and Comirnaty® (10 microgram/dose) diluent CNS.

We are continuing to work with CNS manufacturers to align pack sizes to vaccine quantities, which would remove the need for this logic in the future.

Should your site require additional CNS due to any shortages in supply, then additional volumes can be ordered through the Ordering Platform. Consumable orders will be delivered on your site's usual fixed delivery day, (if the order has been placed before your standard order cut-off). If your site requires more CNS before its next delivery, then these would need to be sourced from within your System/Region.

From 31 May, the EECL Helpdesk will no longer be actioning requests to order additional vaccine linked consumables, all orders must be placed via the Ordering Platform.

The process for ordering consumables on the Ordering Platform is the same as for ordering vaccine. A training video is available on the Ordering Platform if additional support is required. To access the training video, click the Training video button; which is located at the top of the Order Platform screen.

Your site can also deselect vaccine linked consumables, such as needles and syringes or Steret wipes, when placing a vaccine order on the Foundry Ordering Platform, if you have an oversupply of any of these items. Deselecting the vaccine consumables bundle is a very quick and simple process, please see the how-to guide which is available on NHS Futures [here](#).

10. REMINDER: rapid insights workshop 19 May 1pm-2pm

The South West NHS England and NHS Improvement team and the South West AHSN would like to invite you to the Rapid Insights Workshop: South West Outreach Covid-19 Vaccination Programme.

During this online session, we will look at the delivery of the vaccine via pop-ups, family clinics and roving models.

We will explore key insights from the Vaccination Programme including:

- Successes
- Challenges
- How we can create a vaccination service for the future
- Using learning to shape subsequent vaccination programmes at system level

By attending, you will help us to capture transferable learning from the various outreach and transient models of vaccination delivery, which can be shared and used to shape national and regional learning and policy in the area of mass vaccination.

Your feedback will be used to create an anonymised report and will not be drawn on to review or reflect upon performance.

Please feel free to forward this invite to any colleagues you think would be interested in attending.

To join the workshop, please click on the link below.

Microsoft Teams meeting

Join on your computer or mobile app

[Click here to join the meeting](#)

[Learn More](#) | [Meeting options](#)

11. Shared learning

11a) Vaccination site learning visits

Over the last few months, the national team's learning visits have been focused on sites that are vaccinating children. We are extremely grateful to these sites for sharing their work, enabling the team to develop and share a number of insights to improve services and support the launch of other cohorts:

- A [summary](#) of initial learning and top tips from the 5-11 Clinically Extremely Vulnerable launch
- Case studies including supporting children and families to access their vaccine in [Nottingham](#) and [London](#); supporting people with additional communication needs in [Hull](#), and working together with schools in [Lincolnshire](#) and [Kirklees](#)
- A [webinar](#) on 23 March shared learning from the launch of the 5-11 at risk. Presentations included pre vaccination triage, use of play specialists in design and delivery of vaccination services and safeguarding
- Locally developed supporting resources such as [how to hold your child during a vaccination](#), [needle phobia help sheet](#) and a [social story - vaccination process walkthrough](#). The full list is available [here](#).

During June, we would like to hear about the following:

- Initiatives to support the immunosuppressed or other vulnerable group to access their COVID-19 vaccination (whether this was intentional or an un-intention 'gain')
- Learning from moving or opening sites that could help others with autumn planning
- Learning from the Omicron surge.

If your site would like to share your insights, please contact sarah.heneker1@nhs.net to discuss arranging a learning visit from the national team.

11b) Case studies

The COVID-19 Vaccination Programme Improvement Hub publishes [case studies](#) to share learning and improvement work across the programme. A new case study is available which

captures 'Reducing clinical assessment and consent times at a vaccination centre'. Please see the full case study [here](#).

If you have an improvement or shared learning case study you would like to share, please email c6.cag@nhs.net.

11c) Vaccination programme shared learning community webinar

The recording of the shared learning webinar from Tuesday 3 May, 'Real-time data entry for vaccination events – why it matters and how to do it really well', is available to [view](#) on the [Improvement Hub](#).

The next webinar will take place on Wednesday 1 June at 3:00pm (details will be available shortly). To register for the webinar, please use the following link – [registration](#) or see the [Improvement Hub calendar](#) for further details.

Previous Learning Community Webinars can be accessed on the [Improvement Hub](#).

11d) Help us improve booking management for flu vaccinations

The NHS Vaccines Programme is conducting user research with staff members from **GP-led sites and community pharmacies** to understand how they manage flu vaccination bookings, either alongside COVID19 vaccinations, or even if they don't offer COVID19 vaccinations (i.e. NBS users and nonusers). We would be keen to speak with either clinical leads or someone who would be responsible for **setting up and organising flu clinics**.

Interested in taking part? Please kindly fill out this [short survey](#) so we can get to know a bit more about your site and send an invitation to join an interview at the most convenient date and time for you.

12. Resources

12a) Royal College of Nursing resources

The Royal College of Nursing (RCN) [immunisation pages](#) have been updated with additional useful resources and guidance for wider immunisation, including Immunisation services delivery: [Practical and clinical guidance for vaccine administration](#).

12b) COVID-19 vaccine fact cards available to help increase confidence and uptake

Fact cards featuring trusted health experts addressing common topics of concern about COVID-19 vaccines are available to support the promotion of vaccination and engagement with Black African and Black African Caribbean communities. [Download the vaccination fact pack](#) on the COVID-19 Vaccine Equalities Connect and Exchange Hub on FutureNHS, or email england.vaccination-equalities@nhs.net.

12c) Cohort Eligibility and Operational Status

[This resource](#) has been reviewed. This week there have been no changes within the programme that need to be reflected in this resource, therefore the version number and dates are the only amendments.

12d) Making Every Contact Count: Online Resource Directory

The team supporting the Making Every Contact Count (MECC) have created an [online resource](#) on the NHS futures page to bring together resources, tools and guidance to support implementation of MECC interventions at Vaccination sites, (posters, leaflets and information) with a focus on the Core20 PLUS5 clinical areas.

12e) Reducing vaccination wastage – top tips

- **Plan in advance** the daily requirement of vaccine – consider the number of booked appointments, number of vials, timing of your vaccine delivery and staffing requirements.
- **Advance calls to confirm attendance** – contact participants ahead of their appointment time to remind / confirm their attendance, this is especially useful for the afternoon bookings to calculate the remaining volume of vaccine which needs to be drawn.
- **Contact DNAs** - offer a walk-in appointment later in the day.
- **Operate a cancellation list** – review cancellations on NBS to vaccine volume planning and have a list of customers who are happy to be contacted to come in for a vaccine at short notice.
- **Utilise anticipated spare vaccine** – consider vaccinating housebound patients at the end of the day.
- **Support customers with bookings** - plan the utilisation of the full vaccine vial by helping customers to book their appointment at times of low demand.
- **Prepare a reduced quantum of vaccine** – to account for potential cancellations and no shows. Some sites work on an uptake of 60% of booked appointments, if more customers arrive then more can be prepared accordingly.

13. Updates from other areas of the programme

- [Latest LVS Updates](#)
- [Latest Vaccination Centre Updates](#)
- [Equalities Connect and Exchange Hub: Weekly Update](#)
- [Workforce and Training update](#)
- [Clinical Updates](#)

NHS England and NHS Improvement
South West

