Management of COVID-19 Vaccine Vaxzevria® (AstraZeneca) Guidance at Vaccination Clinics

This document is under regular review and will be updated when relevant new information becomes available. Please check www.immunisation.ie for current version

1. Background

Vaxzevria® (AstraZeneca) will be delivered at a temperature of +2 °C to +8 °C by the National Cold Chain Service (NCCS) to the site. The site will take ownership of the vaccine upon delivery.

Additional information about the vaccination programme is provided in the document Clinical Guidance for COVID-19 Vaccination available at www.immunisation.ie

EMA has recommended granting a conditional marketing authorisation for Vaxzevria® (AstraZeneca) on the 29th January 2021. The product information approved by the CHMP contains prescribing information for healthcare professionals can be found below:

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf

2. Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of the Vaxzevria® (AstraZeneca). Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of the Vaxzevria® (AstraZeneca) at the vaccination centre level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Safe vaccine handling including management of shelf life reduction processes following first puncture of the vial.
- Vaccine decommissioning
- Stock reconciliation

The document provided may be used as templates to be adapted for local use or may be used as reference sources to check that existing local procedures are robust and comprehensive.

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

- Read the temperature of the fridge/s,
- Record maximum , minimum and current temperature
- Reset after recording

For additional information the following document may be consulted:
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf Vaxzevria® (AstraZeneca) will be delivered at a temperature of +2 °C to +8 °C
Each box will contain 10 multidose vials (MDV). Receipt delivery of stock and scan stock onto the system as you unpack the delivery

Place the stock immediately in the fridge at a temperature of +2 °C to +8°C. The vials should remain in their original box to be protected from light.

4.2 Safe handling

Vaxzevria® (AstraZeneca) comes ready to use, and each vial contains at least 10 doses. One dose (0.5 mL) contains not less than 2.5 x 10^8 infectious units (Inf. U).

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose(s). The National Immunisation Advisory Committee advises that if more than ten doses can be safely and accurately withdrawn from a vial they can be used as valid doses. There should be no pooling of excess vaccine volume from multiple vials.

The shelf life of the unopened vials is less than 6 months and they should remain in their original boxes in the fridge until the time of usage.

From the time of vial opening (first needle puncture) to administration, the product may be kept and used at temperatures up to 30°C for a single period of up to 6 hours. After this time period, the product must be discarded.

4.3 Vaccine decommissioning

COVID-19 vaccines will be serialised and once the serialised boxes become available these boxes will require to be decommissioned. Decommissioning will be done by Hospitals and by Retail Pharmacies or by NCCS as per Article 23.

COVID-19 vaccines delivered to GPs, HSE locations including Vaccination Clinics will be decommissioned by the NCCS as these locations are exempt.

Vaxzevria is serialised and must be decommissioned.

4.4 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for.

Vaxzevria® (AstraZeneca) Reconciliation Form can be found at the following links below. Please note they are editable PDF

- Vaxzevria® (AstraZeneca) -Vaccine Reconciliation Form for GP practices Version 1.0

https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/astrazenecavaccinereconciliationfor m.pdf

- Vaxzevria® (AstraZeneca) - Vaccine Reconciliation Form for clinic settings Version 1.0

https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/azvaccrecnongp.pdf

5. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment

These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered/supplied. A national distribution service will provide all necessary supplies, to handle, prepare and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

Other Equipment includes:

- **Anaphylaxis Kits**

Refer to National Immunisation Advisory Committee Guidelines
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

The epinephrine will be purchased and FMDed by a pre-determined community/ hospital pharmacy as agreed by the lead governance organization CHO/HG.

- **Storage Equipment**

A pharmaceutical fridge must be used to store vaccines. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2^{O}C to prevent freezing and remain less than +8^{O}C. The temperature should be set to maintain +5^{O}C +/- 3^{O}C.

Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be performed. The physical stock count of the Vaxzevria® (AstraZeneca) should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal.

All waste must be handled in such a way as to prevent theft and /or misuse, both on site and after removal from the site.

Dispose empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

Records of vaccine dose reconciliation should be maintained at the site.

7. Health & Safety

There are no special handling requirements for routine handling of Vaxzevria® (AstraZeneca). However, Vaxzevria® (AstraZeneca) contains genetically modified organisms (GMOs). Should a spillage occur this should be disinfected with an appropriate antiviral disinfectant (active on coronavirus). To note that genetically modified organisms (GMOs) refers to the chimp adenovirus vector system which has been inactivated and cannot replicate *in vivo.*

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.