Guidance for management of Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccine from the time of delivery at sites up to the time of administration.

1. Background

Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccines are delivered by the HSE National Cold Chain Service (NCCS) at a temperature of +2 ºC to +8 ºC.
The SmPC is available at:
https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf

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

2. Responsibilities

The Responsible Person should ensure that Nuvaxovid XBB.1.5 Covid-19 vaccines are managed as outlined in this guidance document.

3. Scope

The scope of this document is to provide a set of standardised procedures for the management of Nuvaxovid XBB.1.5. Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of Nuvaxovid XBB.1.5 at the vaccination clinic level, and to provide supporting guidance in relation to:

- Receipt of vaccine
- Vaccine decommissioning
- Shelf-Life
- Storage
- Presentation and preparation
- Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment
- Stock Control, Security & Monitoring of Wastage
- Health & Safety

The documents 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 Receipt of vaccines

- Prior to receipt of vaccine delivery, ensure the fridge temperature is between +2 °C and +8 °C.
- Sign for receipt of the vaccines. Vaccines will be at a temperature of +2°C to +8°C when delivered by the NCCS.
- Check against the delivery docket.
- Place the vaccines immediately in a pharmaceutical fridge.

For additional information please see the following document:
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

4.2 Vaccine Decommissioning

Nuvaxovid XBB.1.5 (Novavax) COVID-19 vaccines boxes have been decommissioned by the NCCS.

4.3 Shelf-Life

- **4.3.1 Expiry date**:

Expiry date is stated on the vial label and the carton. Do not use the vaccine after the expiry date.

- **4.3.2 Discard date and time**

The discard date and time must be written on the vial once the vial is initially punctured. This is calculated by adding **6 hours** to the time of the initial puncture and this time and date must be recorded on the vial. The vaccine can be stored between +2°C to +25°C during this 6 hour period.
From a microbiological point of view, after first opening (first needle puncture), the vaccine should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

4.4 Storage

Unopened vial

- Store in a refrigerator (+2°C to +8°C).

- Do not freeze.
- Keep the vials in their original outer carton in order to protect from light.

An unopened vial can be stored at +2°C to +8°C, protected from light, within the product shelf life stated on the vial label and the carton.

Unopened Nuvaxovid XBB.1.5 vaccine has been shown to be stable for up to 12 hours at + 25°C. Storage at + 25°C is not the recommended storage condition but may guide decisions for use in case of **temporary temperature excursions** during the storage at +2°C to +8°C.

Punctured vial

Chemical and physical in-use stability has been demonstrated for 6 hours at room temperature (maximum +25°C) from the time of first needle puncture to administration.

4.5 Presentation and Preparation

Nuvaxovid XBB.1.5 is presented as a multi-dose vial containing 2.5 ml of dispersion in each vial (type I glass) with a stopper (bromobutyl rubber) and an aluminium overseal with blue plastic flip-off cap. .
Each carton of Nuvaxovid XBB.1.5 contains two multi-dose vials

Preparation for use

- The vaccine comes ready to use.
- Unopened vaccine should be stored at +2°C to +8°C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Each multi-dose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration. Do not administer the vaccine if either are present.
- Record the discard date and time on the vial label. The discard time is 6 hours after first puncture when stored at room temperature (maximum +25°C).
- Gently swirl the multi-dose vial before and in between each dose withdrawal. Do not shake.

Administer the vaccine

- An overfill is included per vial to ensure that a maximum of 5 doses (vial of 2.5 ml) of 0.5 ml each can be extracted.

- Each 0.5 ml dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

5. Consumables, Patient Information Leaflets (PILs), Record Cards and Other Equipment

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/schoolproghcp/protocols/anaphylaxis2016.pdf

The adrenaline will be provided by a pre-determined community/ hospital pharmacy as agreed at a local level.

Storage Equipment: A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at +5 ^{O}C +/- 3 ^{O}C, and alarms should take into account the need to maintain the temperature above +2 ^{O}C and less than +8 ^{O}C.

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

6. Stock Control, Security and Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should be completed and it 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.

Unopened vials (in original cartons) must be returned to NCCS for destruction following the routine protocol for all expired /damaged vaccines.

Dispose empty or partial 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 be defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

7. Health and Safety

There are no special requirements for routine handling and dealing with spillages of Nuvaxovid XBB.1.5 COVID-19 vaccine.
Health and safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.