COVID-19 VACCINE Public Health Advice

Management of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine 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 the current version.

1. Background

Comirnaty® (Pfizer/BioNTech) COVID-19 will be delivered at a temperature of +2 °C to +8 °C by the NationalCold Chain Service (NCCS) to the site. The site will take ownership of the vaccine upon delivery.

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

Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine was granted conditional marketing authorisation by the European Commission on 21 December 2020: The SmPC is accessible at https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

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 Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine. Separate documents are available for other COVID-19vaccines.

4. Purpose

The purpose of this document is to outline the management of Comirnaty® vaccine at the vaccination centre level and to provide supporting guidance in relation to:

- Safe and temperature controlled storage,
- Safe vaccine handling and management of shelf life reduction processes following dilution.
- Transportation of vaccines
- Stock reconciliation

The documents provided may be used as templates to be adapted for local use or may be used as referencesources 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

NCCS will deliver Comirnaty® at a temperature of +2 °C to +8 °C in their original carton, or pre-packed into smaller labelled cartons. 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 an upright position** and in the box in order to protect from light. The vials should not be refrozen.

4.2 Vaccine decommissioning

Unopened tray of 195 vials may require decommissioning by Hospitals and Retail Pharmacies. The vaccines will be decommissioned by the NCCS for the Article 23 locations e.g., GPs and HSE locations including Vaccination Clinics.

4.3 Safe handling

Comirnaty® comes in a multi dose vial and **must be diluted with 1.8ml of sodium chloride (0.9%) solutionfor injection before use**. Each vial contains 0.45ml antigen and after dilution will contain 2.25 ml and therefore up to 7 doses of 0.3mL may be available. One dose (0.3mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

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 (NIAC) advises that if more than sixdoses can be safely and accurately withdrawn from a vial they can be used as valid doses.

DO NOT pool excess vaccines from multiple vials.

Undiluted vial

An **undiluted vial** of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to one month (31 days) at temperatures between +2°C and +8°C. Boxes will be labeled by the NCCS with the **USE BEFORE date and time** reflecting this new extended storage shelf life. This date should be recorded in the patient's record. Prior to use, the unopened vaccine can be stored for up to 2 hours at room temperature up to 30°C.

The following information is intended to guide healthcare professionals only in case of temporary temperature excursion.
Stability data indicate that the unopened vial is stable for up to:

- 24 hours when stored at temperatures from -3 °C to +2 °C
- A total of 4 hours when stored at temperatures from 8 °C to 30 °C; this includes the 2 hours at up to 30 °C detailed above.

Diluted medical product

Once diluted a "**DISCARD** time" is applied and written on the vial which is 6 hours from the time of dilution.

Chemical and physical in-use stability, has been demonstrated for 6 hours at 2 °C to 30 °C **after dilution**. From a microbiological point of view, the product should be used immediately. If not used immediately, in-usestorage times and conditions are the responsibility of the user.

Do not use the vaccine if the vial contains particulates or if the solution is discolored.

To note:

- The **USE BEFORE** dates and time of the vaccine must be recorded in the IT system (as stamped on the vaccine box delivered by the HSE National Cold Chain Service).
- The batch number of the vaccine must be recorded.
- The batch number of the 0.9% Sodium Chloride solution must also be recorded.

4.4 Transportation of vaccines

The total or cumulative duration of transit of the **undiluted** product at temperatures between +2 °C and +8 °C,must not exceed 12 hours. The 12 hours must include all travel time commencing at time of departure from NCCS to the vaccination centre and all other transportation of the undiluted vaccine thereafter. These times must be taken within the **USE BEFORE** dates and time. Each delivery box is over labelled with time of departure label which is stamped when leaving NCCS and is completed by driver at time of handover to recipient.

An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials, which aretemporarily knocked over, may still be used.

During the 6 hours in-use period after dilution the medical product can be transported.

There is no stability data for vials stored or transported on their side.

For additional information the following document may be consulted:

HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes (Updated 15/04/2020)

4.5 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reasonare accounted for. Reconciliation forms for Comirnaty® (Pfizer/BioNTech) COVID-19 in an editable PDF format can be accessed at the following links

- Comirnaty® -Vaccine Reconciliation Form for GP practices Version 1.0 19 January 2021
- Comirnaty® -Vaccine Reconciliation Form for clinic settings Version 1.0 4 March 2021

5. Consumables, Patient Information Leaflet (PIL) & RecordCards 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 includedin 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 epinephrine will be purchased and FMDed by a pre-determined community/ hospital pharmacyas 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 alarmsshould take into account the need to maintain the temperature above +2 °C to prevent freezing and remain less than +8 °C. The temperature should be set to maintain +5 °C +/- 3 °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 vaccine 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 and dealing with spillages of Comirnaty ® COVID- 19 vaccine.

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