# Management of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine Guidance at Local Hubs

***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

The vaccine supply chain is managed by the National immunisation Office (NIO) and The HSE National Cold Chain Service (NCCS). The HSE will take ownership of the vaccine upon delivery by the manufacturer to the HSE National Cold Chain Service. Onward delivery to the hubs or points of administration will at temperature of +2 $^{O}$C to +8 $^{O}$C.

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:
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

## 2 Scope & Purpose

The scope of this document is limited to the Comirnaty®( Pfizer/BioNTech) COVID-19 Vaccine. Separate documents will be specially prepared for other COVID-19 vaccines.

The purpose of this document is to outline the medicines management responsibilities at local level (hub), and to provide supporting guidance and resources in relation to:

- Safe storage and distribution, including temperature controlled storage, safe handling, stock control, and stock reconciliation
- Oversight of vaccine handling and preparation, including management of shelf life reduction processes following reconstitution

It aims to promote consistency of practice by providing flow diagrams outlining a stepwise approach to implementing processes to receive, store and issue vaccines, and to oversee vaccine handling processes by clinical staff.

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.

## 3 Operating at Hub

At the time of writing it is known that Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to 120 hours at temperatures between +2 $^{O}$C and +8 $^{O}$C, followed by an additional 2 hours at room temperature.

After dilution it should be used as soon as practically possible and within 6 hours. The total or cumulative duration of transit of the undiluted product at temperatures between +2 $^{O}$C and +8 $^{O}$C, must not exceed 12 hours. The 12 hours must include the travel time from NCCS in Dublin to the hub and all other transportation thereafter. These times are to be taken within the 120 hour shelf life. The models in this document are designed to minimise movement of the vaccine once it has been thawed.

The vaccine vials will come in their original carton (over-labelled with a “use before” date and time), or pre-packed into smaller labelled cartons and that they remain at 2-8 $^{O}$C, until the point of vaccination.

**Implementation of effective process control is essential to ensure that vaccines are stored correctly and appropriate “use before” and “discard” dates and times are allocated.**

## 4 Vaccines, Consumables & Other Equipment

A national distribution service will purchase and deliver 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.

### 4.1 Vaccines

NCCS will deliver Comirnaty® to the point of administration or the designated Hub requiring storage between +2 $^{O}$C and +8 $^{O}$C.
The vaccine comes in a multi dose vial and must be diluted before use. Each vial contains 0.45ml antigen and contains up to 7 doses of 0.3mL after dilution. One dose (0.3mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

## 5 Consumables, Patient Information Leaflet & Record Cards

These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered.

### 5.1 Anaphylaxis Kits

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

### 5.2 Labels for Cartons

Labels and cartons will be provided with vaccines to hubs where off-site vaccination clinics will be held and to where there is a requirement to carry a small number of vials.

### 5.3 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.

## 6 Safe Storage & Distribution

### 6.1 Stock Control, Security & Monitoring of Wastage

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. Waste vaccines and empty vials must be disposed of 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. Copies of these will be requested periodically by the Chief Pharmacist in the NIO.

### 6.2 Validation & Monitoring of Cold Chain

Comirnaty® vaccine requires storage at +2$^{O}$C to +8$^{O}$C.

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

### 6.3 Health & Safety

Pfizer/BioNTech reports that neither special handling requirements for either routine handling nor dealing with spillages is necessary.

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

## 7 Vaccine Handling & Preparation

Each step of this process changes the vaccine characteristics and therefore each step will require a reduction in the shelf life. A diligent process is necessary to ensure the correct end date/time is adhered to, and that the vaccine is safe and effective at the point of use.

**Process flow 1** shows a process of packing thawed vials at a hub and transport to vaccination locations or points of administration

**Process flow 2** shows an overview of the vaccine pathways during vaccination sessions. This is supported by a SOP, a work instruction for syringe preparation, and a sessional checklist for supervision of the vaccine handling during the vaccination session.

**Transportation time:**
Vaccines should be moved in compliance with the requirement for a maximum of 12 hours transportation time.

Transportation time: a maximum of 12 hours - cumulative time from the start of when the thawed vaccine is moved from the HSE National Cold Chain Service to the delivery location and any subsequent movement of the vaccine until the time of vaccine administration.

## Process Flow 1: Transportation of Vaccines

Prepare a cool box for transport at 2-8°C

Cool boxes must be suitable for the duration of use and mode of transport. Consider the volume of vaccines carried compared to normal vaccination clinics and adjust the number of cold chain packs appropriately. Consider the duration for which the cool box will be required.

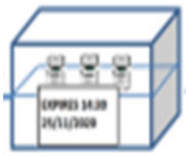
Position the coolbox in or as close as possible to the assembly location

Ideally assembly will be performed inside a cold store if issuing from fridge:

- Work quickly to minimise exposure of the vaccines to room temp. Consider working in pairs
- Avoid frequent fridge door openings and allow fridge temperature to recover between openings
- Place a temperature monitoring probe into the cool box.

Select and pack the required number of thawed vials


Label with
- contents
- expiry date/time (from outer carton from which the vials have been removed)



The vials must be securely held in an upright position to minimise movement in transport, and should be protected from light.

Secure the new vial box into the coolbox

The coolbox packing pattern should be defined locally to

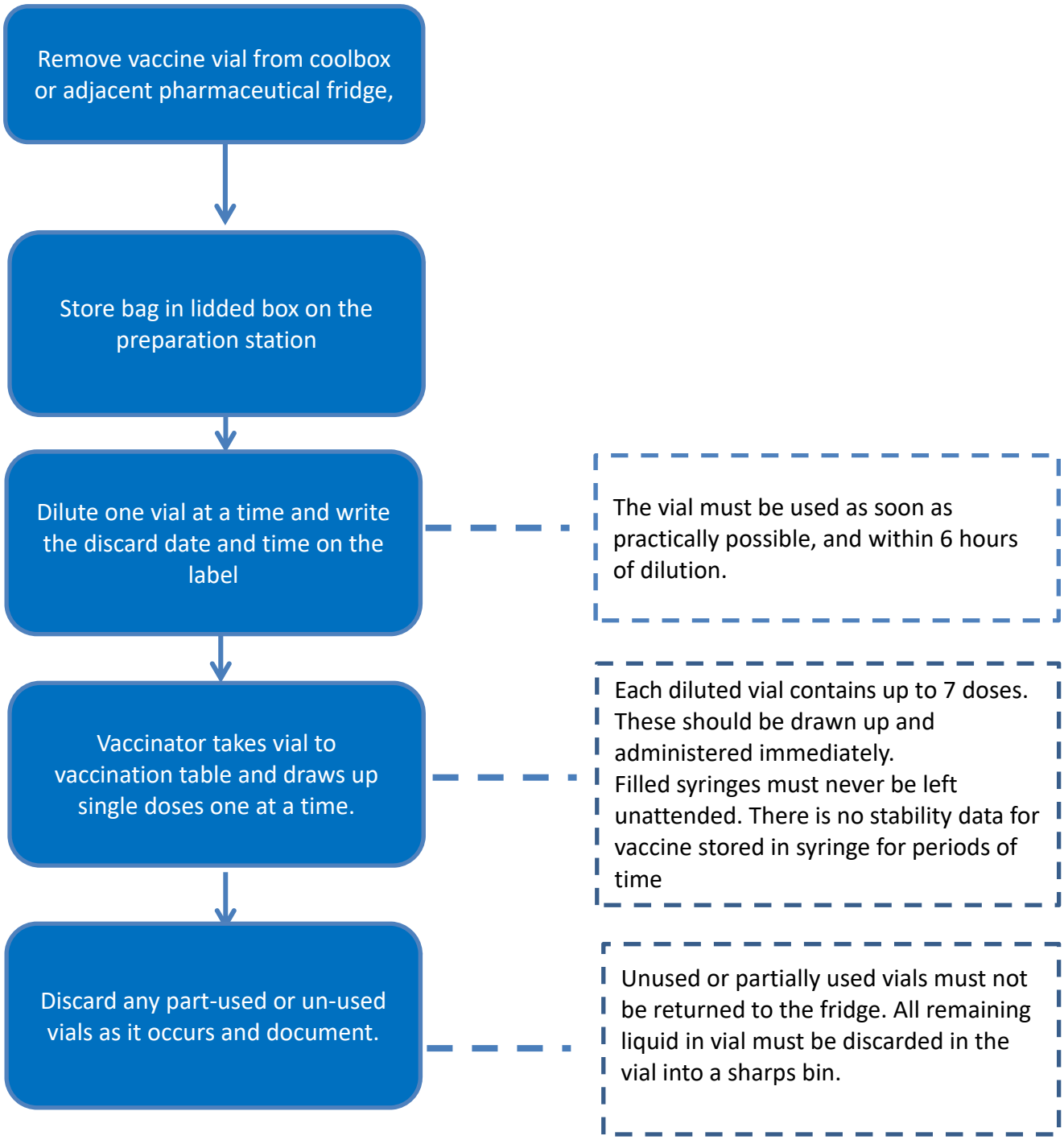
- Minimise movement of the vials
- Maintain temperature between +2°C and +8°C.

Transport to the vaccination location

The thawed, packed vaccine may be transported for up to 12 hours during the 120 hour post-thaw shelf life. It must take into account any journeys the vaccine may have already taken in its thawed state.

Agitation of the vials should be minimised throughout this time.

**Process Flow 2: Overview of the Vaccine Pathways during Vaccination Sessions**



**COVID-19 Vial Traceability Session Form**

| Batch Number | Use before Date / Time | Discard Date and Time on vial (6 hours post dilution) | Disposal time to sharps bin | Excursion comment |
|---|---|---|---|---|
| e.g. AB 12345 | 04/01/2021 15:15 | 01/01/2021 18:15 | 01/01/2021 15:25 | |
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