Guidance for management of Comirnaty (Pfizer) COVID-19 mRNA Vaccine from time of delivery at sites up to the time of administration.

This document contains two sections:

<u>Section 1</u> contains general information for all Comirnaty presentations

1. **Background**
2. **Responsibilities**
3. **Scope**
4. **Purpose**
5. **Consumables, Patient Information Leaflet (PIL) & Record Cards and other Equipment**
6. **Stock Control, Security & Monitoring of Wastage**
7. **Health & Safety**

<u>Section 2</u> contains 3 appendices with specific details pertaining to each vaccine product.

i. **Appendix 1 refers to vaccine for 12 years and older.**
Comirnaty LP.8.1 30 micrograms/dose dispersion for injection–Ready to Use (RTU) – Grey cap

ii. **Appendix 2 refers to vaccine for children aged 5 to11 years.**
Comirnaty LP.8.1 10 micrograms/dose dispersion for injection- Ready to Use (RTU) – Blue cap

iii. **Appendix 3 refers to vaccine for infants and children aged 6 months to 4 years.**
Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection - Requires Dilution before use– Yellow cap

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

1. Background

Comirnaty COVID-19 Vaccines are delivered by the HSE National Cold Chain Service (NCCS) at a temperature of +2 ˚C to +8 ˚C, and therefore in a thawed state. The NCCS will update the expiry date and affix a “HSE SCAN ME” label detailing the new reduced shelf life (= USE BEFORE date and time). **Do not re-freeze.**

Comirnaty formulations (GREY, BLUE and YELLOW caps) have a number of specifications in common. All products are multidose vials and contain Trometamol.

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

All SPCs are accessible at:
https://www.medicines.ie/medicines/list/all/page-1/per-page-25?query=comirnaty

2. Responsibilities

The Responsible Person should ensure that Comirnaty 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 Comirnaty COVID- 19 vaccines at all vaccination sites

4. Purpose

The purpose of this document is to outline the management of Comirnaty vaccines and to provide supporting guidance in relation to:

4.1 Receipt of vaccine

4.2 Vaccine decommissioning

4.3 Shelf-life

4.4 Storage and transportation

4.5 Presentation and preparation

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

- Upon arrival at the site, record the maximum, minimum and current temperature of the fridge(s), and reset after recording.
- Prior to receipt of vaccine delivery, ensure the 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 (Note: the expiry date on the docket may differ to printed expiry on carton and vial- the delivery docket carries the updated and correct expiry date).
- Scan or record the details of the HSE SCAN ME label and immediately place the vaccines in the fridge.

  For additional information, please see the following document:

  - HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines Updated 9 September 2024
  - HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes Updated 28 August 2024.

4.2 Vaccine Decommissioning

All boxes have been re-labelled and decommissioned by the NCCS.

4.3 Shelf-Life

4.3.1 Expiry date:

Comirnaty LP.8.1 formulations have a shelf life of 18 months when stored in ULT freezers (-90˚C to - 60˚C).

4.3.2 USE BEFORE date and time

The USE BEFORE date and time reflects the duration the unopened vial can be stored at +2 ˚C to +8 ˚C, which is **up to 10 weeks**. All boxes containing Comirnaty vaccines will be labelled by the NCCS with a USE BEFORE date and time label.

The USE BEFORE date and time specified on the label indicates the time by which the vial **must be used**, irrespective of the expiry date on box or vial.

Record the USE BEFORE date in the patient's record and on the National Immunisation InformationSystem (NIIS) formerly known as COVAX.

4.3.3 DISCARD date and time

Discard date and time must be written on the vial once the vial is initially punctured. This is

calculated by adding **12 hours** to the time of first puncture. The vaccine can be stored at temperature between +2 ˚C and +30 ˚C during this period.

From a microbiological perspective, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

NOTE: The discard time cannot exceed the USE BEFORE date and time. If the time remaining between first puncture and USE BEFORE date and time is less than the allowed discard time of 12 hours, then the discard time must reflect the USE BEFORE date and time. All doses must be administered before the USE BEFORE date and time, or else doses must be discarded.

4.4 Storage & Transportation

Vials can be handled in room light conditions.

An appropriate container should be used for transportation to minimize the potential for vials to be jostled. If vials are inadvertently bumped or dropped, they should be returned to the upright position, however the risk to the product is minimal and vials which are dropped may still be used. When a vial is dropped outside of trays, the vial should be inspected and if no damage is observed it may be considered safe to use. If the vial is already punctured or diluted, or if a syringe containing vaccine (from a vial) is dropped, microbiological risk must be considered when determining if the vaccine is acceptable to use.

Unopened vials can be stored and transported for 10 weeks at +2 ˚C to +8 ˚C within USE BEFORE date and time). Prior to use, unopened vials can be stored for 12 hours prior to first puncture at room temperature (+8 ˚C to +30 ˚C)

Vials can be stored for 12 hours after first puncture or dilution (for Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection), at temperature between +2 ˚C and +30 ˚C, which includes up to 6 hours transportation time.

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 10 weeks when stored at temperatures from -2 °C to 2 °C, within the 10-week storage period between +2 °C and +8 °C and up to 24 hours at temperatures of +8 °C to +30 °C, including up to 12 hours following first puncture.

4.5 Presentation and Preparation

All formulations are packed in original boxes of 10 vials.

- Vials of Comirnaty LP.8.1 30 micrograms/dose dispersion for injection (**GREY cap**) contain six doses
- Vials of Comirnaty LP.8.1 10 micrograms/dose dispersion for injection (**BLUE cap**) contain six doses
- Vials of Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection (**YELLOW cap**) contain three doses (after dilution).

Vial verification is essential.

- Comirnaty LP.8.1 30 micrograms/dose dispersion for injection–Ready to Use (RTU) – **GREY cap**
- Comirnaty LP.8.1 10 micrograms/dose dispersion for injection –Ready to Use (RTU) – **BLUE cap**
- Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection – Requires Dilution – **YELLOW cap**

Preparation: **c.f. Individual Presentation Appendices 1 to 3**

Where diluent is required, only sterile sodium chloride 9 mg/mL (0.9%) solution for injection. Bacteriostatic saline or other diluents must **NOT** be used.

Do not pool excess vaccine from multiple vials.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

5. Consumables, Patient Information Leaflet (PIL) & 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 at

- Anaphylaxis: Immediate Management in the Community. NIAC (2023), Immunisation Guidelines for Ireland.

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 °C +/- 3 °C, and alarms should take into account the need to maintain the temperature above +2 °C and below +8 °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 completed, and it should match the stock count recorded on the IT system.

Sites must 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 of 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 have their labels defaced using permanent black marker pens, and be placed into appropriate waste sacks for disposal, as soon as possible after they become empty.

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.

COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified) Formulations Guide for different age groups

12 years and older

	12 years of age and older, Ready to use
Vial Cap Colour & Formulation	 LP.8.1
Dosage	LP.8.1: 30 mcg of mRNA encoding LP.8.1
Injection Volume per Dose	0.3 mL
Dilution	NO DILUTION
Amount of Diluent Needed per Vial*	NO DILUTION
Doses per Vial	Multi-dose vial contains 6 doses
Fill Volume per Vial	2.25 mL for multi-dose vial
Ultra-Low Temperature (ULT) Freezer (-90 °C to -60 °C)	LP.8.1: 18 months (shelf life)
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours

5 to 11 years

	5 to 11 years old, Ready to use
Vial Cap Colour & Formulation	 LP.8.1
Dosage	LP.8.1: 10 mcg of mRNA encoding LP.8.1
Injection Volume per Dose	0.3 mL
Dilution	NO DILUTION
Amount of Diluent Needed per Vial*	NO DILUTION
Doses per Vial	Multi-dose vial contains 6 doses
Fill Volume per Vial	2.25 mL for multi-dose vial
Ultra-Low Temperature (ULT) Freezer (-90 °C to -60 °C)	LP.8.1: 18 months (shelf-life)
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours

6 months to 4 years

	6 months to 4 years old, Dilute to use
Vial Cap Colour & Formulation	 LP.8.1
Dosage	LP.8.1: 3mcg of mRNA encoding LP.8.1
Injection Volume per Dose	0.3 mL
Dilution	Dilution required
Amount of Diluent Needed per Vial*	1.1 mL
Doses per Vial	3 doses per vial (after dilution)
Fill Volume per Vial	0.48 mL
Ultra-Low Temperature (ULT) Freezer (-90 °C to -60 °C)	LP.8.1: 18 months (shelf-life)
Freezer Storage Time (-25 °C to -15 °C)	DO NOT STORE
Refrigeration Storage Time (2 °C to 8 °C)	10 weeks
Room Temperature (8 °C to 30 °C)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2 °C to 30 °C)	Discard after 12 hours

Appendix 1

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection – Ready to Use (RTU) – Grey cap

a. Comirnaty LP.8.1 30 micrograms/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older.
b. One dose (0.3 ml) contains 30 micrograms of mRNA encoding LP.8.1, a COVID−19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).
c. Verify that the vial has a grey plastic cap, and the product name is Comirnaty LP.8.1 30 micrograms/dose dispersion for injection (12 years and older).

The following is applicable to Comirnaty LP.8.1 30 micrograms/dose dispersion for injection:

- The vaccine is Ready To Use- **DO NOT DILUTE.**
- The vaccine does not contain preservative and is provided as a multiple dose vial.
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 6 doses.
- Each dose is 0.3 ml.
- Do not pool excess vaccine from multiple vials.

Preparation: Verify that the vial has a GREY plastic cap

a. Gently mix by inverting vials 10 times prior to use. Do not shake.
b. Prior to mixing, the dispersion may contain white to off-white opaque amorphous particles.
c. After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible.
d. Do not use the vaccine if particulates or discolouration are present.
e. One vial contains 6 doses of **0.3 ml** (low dead-volume syringes and/or needles should be used).
f. Each dose must contain **0.3 ml** of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of **0.3 ml**, discard the vial and any excess volume.
g. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C.
h. After first puncture, the vial should be stored between +2 °C to +30 °C.
i. Record the appropriate discard date/time on the vial.
j. Discard any unused vaccine 12 hours after first puncture.

Appendix 2

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection – Ready to Use (RTU) – Blue cap

a. Comirnaty LP.8.1 10 micrograms/dose dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.
b. One dose (0.3 ml) contains 10 micrograms of mRNA encoding LP.8.1, a COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).
c. Verify that the vial has a blue plastic cap and the product name is Comirnaty LP.8.1 10 micrograms/dose dispersion for injection (children 5 to 11 years).

The following is applicable to Comirnaty LP.8.1 10 micrograms/dose dispersion for injection

- The vaccine is Ready To Use- **DO NOT DILUTE**.
- The vaccine does not contain preservative and is provided as a multiple dose vial.
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 6 doses.
- Each dose is 0.3 ml.
- Do not pool excess vaccine from multiple vials.

Preparation: Verify that the vial has a BLUE plastic cap

a. Gently mix by inverting vials 10 times prior to use. Do not shake.
b. Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
c. After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible.
d. Do not use the vaccine if particulates or discolouration are present.
e. One vial contains 6 doses of **0.3 ml** (low dead-volume syringes and/or needles should be used)
f. Each dose must contain **0.3 ml** of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of **0.3 ml**, discard the vial and any excess volume
g. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C.
h. After first puncture, the vial should be stored between +2 °C to +30 °C.
i. Record the appropriate discard date/time on the vial.
j. Discard any unused vaccine 12 hours after first puncture.

Appendix 3

Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection – Dilute to Use – Yellow cap

a. Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.
b. One vial (0.48 ml) contains 3 doses of 0.3 ml after dilution with 1.1 ml of NaCl 0.9% solution for injection. One dose (0.3 ml) contains 3 micrograms of mRNA encoding LP.8.1, a COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).
c. Verify that the vial has a yellow plastic cap, and the product name is Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection (infants and children aged 6 months to 4 years).

The following is applicable to Comirnaty LP.8.1 3 micrograms/dose concentrate for dispersion for injection:

- The vaccine does not contain preservative and is provided as a multiple dose vial.
- Excipients include Trometamol and Trometamol hydrochloride.
- Each vial contains 3 doses
- Each dose is 0.3 ml
- Do not pool excess vaccine from multiple vials.

Preparation: Verify that the vial has a YELLOW plastic cap.

a. Allow the vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
b. Prior to dilution, the dispersion may contain white to off-white opaque amorphous particles.
c. The vaccine must be diluted in its original vial with **1.1 ml sodium chloride 9 mg/ml (0.9%) solution for injection**, using a 21 gauge or narrower needle and aseptic techniques. Do not add more than 1.1 ml of diluent.
   IMPORTANT: regardless of the volume of the diluent vial, it must be used for ONE TIME dilution only (after withdrawal, the remaining diluent must be discarded)
d. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.1 ml air into the empty diluent syringe.
e. Gently invert the diluted dispersion 10 times. Do not shake.
f. The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
g. The diluted vial should be marked with the appropriate discard date and time.

h. After dilution, store at 2 ºC to 30 ºC and use within 12 hours.
i. Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
j. After dilution, the vial contains 1.58 ml from which 3 doses of 0.3 ml can be extracted.
k. Each dose must contain 0.3 ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume.
l. Discard any unused vaccine within 12 hours after dilution.