

Comirnaty (Pfizer) vaccines

Guidance on management of Comirnaty (Pfizer) COVID-19 vaccines

Purpose

A range of Comirnaty (Pfizer) vaccines are approved by the TGA for use in specific age groups as a primary course or a booster dose in accordance with ATAGI advice on COVID-19 vaccination. This guideline provides information specific to the storage, transfer, handling and administration of Comirnaty (Pfizer) vaccines. COVID-19 vaccination providers must refer to the TGA Product Information for management of COVID-19 vaccines. This procedure must be read in conjunction with the following documents:

- [Australia Immunisation Handbook](#)
- [The TGA Product Information](#)
- [ATAGI clinical guidance for COVID-19 vaccine providers](#)
- [ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination](#)
- [The Australian Government COVID-19 vaccines webpage](#)

Vaccine management

Storage in Ultra Low Temperature (-90°C and -60°C)

See: [Management of Pfizer \(COMIRNATY™\) COVID-19 vaccine from shipper to ultra-low temperature freezer](#)

Storage in standard temperature freezers (-25°C and -15°C)

- Some Pfizer COVID-19 vaccines can be stored at -25°C to -15°C. Please check the relevant [TGA product information](#).
- After removing from an ULT shipper or ULT freezer, unopened vials of Comirnaty (Pfizer) vaccine may be able to be stored at -25°C to -15°C for up to two weeks and may be returned to -90°C to -60°C ONCE.
- COVID-19 vaccination providers must ensure local processes are in place to record details of transfers of vial trays from ULT shipper or ULT freezer to standard temperature freezer, and expiry date and time of vial trays stored in a standard temperature freezer.
- For further information see the [TGA Product information](#).

Thawing of vaccine

- For information about maximum time that frozen vials can be at temperatures up to +25°C during transfer, please refer to [TGA Product information](#).

- Vials need to be thawed before use. Once a vial is thawed it should not be re-frozen. Frozen vials should be transferred to a refrigerator at +2°C to +8°C to thaw. Alternatively, frozen vials may also be thawed at room temperature in accordance with TGA Product Information.
- COVID-19 vaccination providers must ensure local processes are in place to record thawing process including time and date removed from ULT freezer, ULT shipper or standard temperature freezer, and expiry time and date of thawed vials.
- For further information please refer to the [TGA Product information](#).

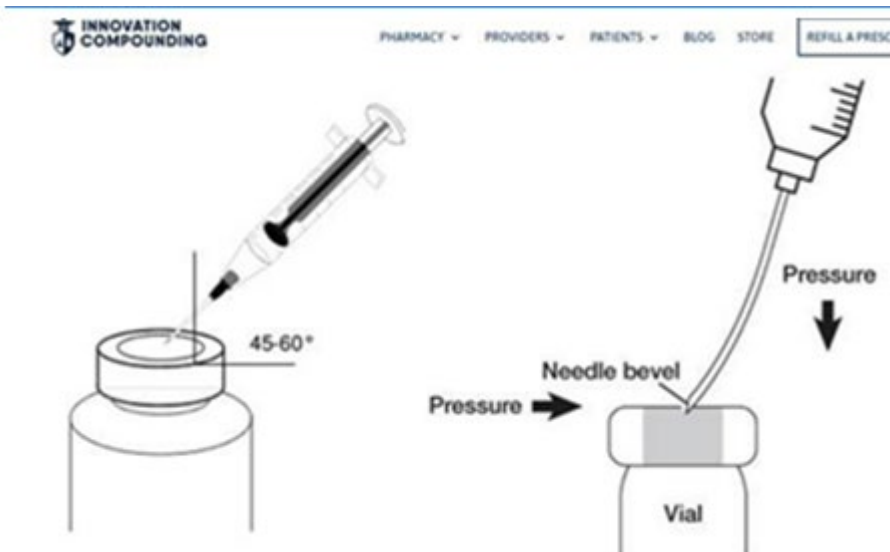
Storage in refrigerator (+2°C and +8°C)

- For the validity of thawed vaccine vials stored at refrigerator temperature (+2°C and +8°C) or at room temperature after removing from freezer, please refer to the [TGA Product Information](#).

Vaccine preparation

COVID-19 vaccination providers must:

- administer Comirnaty (Pfizer) vaccines in line with the [TGA Product information](#) and [ATAGI guidance on the use of multidose vials for COVID-19 vaccination](#).
- ATAGI recommends that punctured vials should preferably be held between +2°C and +8°C. Note: The vial does not contain antimicrobial preservatives therefore 6 hours storage of the punctured vial is recommended unless the vials are prepared using a method that minimises risk of microbial contamination. If the following conditions are met the punctured vial can be managed in accordance with the [TGA Product Information](#). The vial must be prepared:
 - by dedicated trained operators preparing vaccines aseptically
 - in an appropriate clean environment with minimal air movement
 - under the oversight of a pharmacist with experience in aseptic preparation
 - the vaccine is protected from light, returned to the refrigerator and stored at +2°C to +8°C when not in use to further minimise antimicrobial growth.
- To avoid bubble and coring, it is recommended the following technique is utilised for accessing the vials:
 - The needle should be inserted at a 45–60° angle with the opening of the needle tip facing up (i.e. away from the stopper). A small amount of pressure is applied, and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.



Source: [Innovation Compounding – Proper Aseptic Technique to Prevent Coring of Sterile Vials](#)

- ensure local process are in place to record expiry time and date of opened vials and drawn-up syringes. For storage time of open vials and drawn-up syringes, please see the [TGA Product Information](#).

Transportation of vaccine

For local redistribution of unopened/opened vials and pre-drawn doses of Comirnaty (Pfizer) vaccines, please see the [TGA Product information](#).

Any hours used for transport of unopened/opened vials and pre-drawn doses of Comirnaty (Pfizer) vaccines at +2°C to +8°C count against the cumulative storage time of the vaccine at +2°C to +8°C as per the [TGA Product Information](#). The cumulative time in transport must not exceed the cumulative storage time in accordance with the [TGA Product Information](#).

For general information regarding vaccine administration, please refer to the Australia Immunisation Handbook:

- [Preparing for vaccination](#)
- [Administering vaccines](#)
- [After vaccination](#)

For information about preparing and administration of Comirnaty (Pfizer) vaccines, please see

- [Australia Immunisation Handbook](#)
- [ATAGI guidance on the use of multi-dose vials for COVID-19 vaccination](#)
- [The TGA Product Information](#)