MINISTRY OF HEALTH
MANATŪ HAUORA

New Zealand Government

2021 Addendum to National Standards for Vaccine Storage and Transportation Providers 2017 (2nd edition)

COVID-19 Vaccine Immunisation Programme

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Introduction/Background

In 2021, the New Zealand COVID-19 immunisation programme started using the Pfizer/BioNTech messenger RNA (mRNA) COVID-19 vaccine, Comirnaty, which requires ultra-cold storage (-70ºC). This storage is carried out in the vaccine distribution network. Vaccine distribution stores, which may include some district health board (DHB) hospital pharmacies, follow standard operating procedures to ensure the vaccine cold chain is always maintained during storage at their sites and during vaccine transportation to providers. Medicines Control, the regulatory team within the Ministry of Health that oversees the local distribution chain of medicines and controlled drugs, audits licensed premises involved in the distribution of cold chain medicines in New Zealand.

Following an agreement that Comirnaty would become New Zealand's primary COVID-19 vaccine and the approval of -20ºC storage for the vaccine, it has become necessary to provide the addendum to the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)* (National Standards).[1] This addendum applies to all immunisation providers once they have received the vaccine from the national store and must be read in conjunction with the **National Standards**.

The distribution network, that is, from the national store to DHB hospital pharmacies (DHB pharmacies) or vaccination sites, sits outside these National Standards, although compliance with the National Standards is expected in this network. All vaccines sent from the national store will contain a datalogger, which must be checked on arrival. Refer to the *Operating Guidelines for DHBs and Providers – COVID-19 Vaccine Immunisation Programme* for full details about this process.[2]

The Ministry of Health (the Ministry) provides the following clarification to local immunisation / cold chain coordinators and providers, including DHB pharmacies, to help DHBs that hold Comirnaty vaccine in freezer storage achieve cold chain accreditation (CCA)/cold chain compliance (CCC) and give all providers some vaccine-specific information about Comirnaty vaccine in +2ºC to +8ºC systems.

Some DHB pharmacies act as both wholesalers and providers and are subject to both the requirements of the National Standards and this addendum.

CCA/CCC for the freezer storage of vaccines is assessed on the same principles as the +2ºC to +8ºC system and acknowledges that all three key components (people, systems, and process and equipment) must be present and to a set standard to reduce

[1] Ministry of Health. 2019. *National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition)*. Wellington: Ministry of Health. URL: **www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017** (accessed 25 May 2021).

[2] Ministry of Health. 2021. *Operating Guidelines for DHBs and Providers: COVID-19 Vaccine Immunisation Programme*. Wellington: Ministry of Health.

risk and ensure vaccine viability through correct storage and follow-up of any deviations from the standards. The components are:

1. the people managing vaccine manufacture, storage and distribution and those managing the cold chain at the provider level
2. the systems and processes providers use to ensure they monitor the vaccine storage conditions and actions taken if the vaccines are exposed to temperatures beyond the required range
3. the equipment used for storing, transporting and monitoring vaccines from the time the vaccine is delivered to an immunisation provider to the time it is administered to an individual.

People

At least two appointed and named staff will be responsible for monitoring the storage conditions and the stock expiry for any Comirnaty vaccine stored by providers, and the appointed staff must meet the same personnel requirements as outlined in section 5.2 of the **National Standards**.

All staff working with Comirnaty must be familiar with the **National Standards**, this addendum and the **CCA documentation**.

DHB pharmacy staff who are packing vaccines for transport must have appropriate training in the packaging and monitoring requirements for Comirnaty. A courier may be used to transfer Comirnaty vaccine in its undiluted form from a wholesaler to a provider, however, the contracted courier must have an agreement in place around priority delivery and be briefed on the process of receipt of the vaccine by clinical staff at the provider end. DHB pharmacies must have operating procedures that cover the standard packing and transporting process.

Diluted Comirnaty vaccine must be transported by an authorised vaccinator or pharmacist vaccinator and meet the requirements for off-site immunisation as outlined in section 7.3 of the **National Standards**.

Cold chain review group

There is great expertise both locally and nationally related to storing and handling vaccines, however, we acknowledge that circumstances may arise that require thinking 'outside the square' to ensure the continuity of vaccine supply.

When the 'outside the square' requirements do not comply with the National Standards or this addendum, distributors must consult and gain agreement from the cold chain review group. The Ministry is currently undertaking the policy work to determine the accountable roles at the Ministry and the process for convening this group and will pass on the details directly to interested parties as soon as they are available.

The cold chain review group will include:

- the local immunisation / cold chain coordinator
- the DHB pharmacy manager
- the Immunisation Advisory Centre (IMAC) cold chain lead
- appropriate Ministry COVID-19 vaccine immunisation programme personnel

or their delegates.

The DHB distributors will consult with their local immunisation / cold chain coordinator in the first instance if they believe they may need to act outside the standard process.

Systems and process

All providers, including hubs that store and transport Comirnaty vaccine, must have a cold chain policy in place, as outlined in section 6.1 of the **National Standards**.

Packing and transporting vaccines from DHB pharmacies

All providers must follow a documented process for packing of Comirnaty vaccines for transport, and this process must include using a datalogger with external display, as discussed in section 7.3 of the **National Standards**.

DHB pharmacies acting as wholesalers and transporting vaccines via courier must ensure that an appropriate datalogger is used in all transports. The datalogger must have a visible indicator to show if it has remained in range during transport.

Comirnaty vaccine must be transported with a datalogger.

Receiving vaccines from a DHB pharmacy

A clinical lead (as identified in the provider cold chain policy) at the provider site must confirm that the transport datalogger has remained in range and arrange for the datalogger to be returned to the DHB pharmacy for routine downloading.

A set process must be followed for confirming the in-range status of the datalogger at the providers, and if the logger indicator shows it has been out of range, the vaccine must be held in quarantine until the datalogger information has been reviewed and advice given as to the use of that vaccine stock.

In the event of a cold chain breach

If a cold chain breach occurs at a DHB pharmacy, or during transport from a DHB pharmacy, DHB pharmacy staff must complete a reporting form, and this form must be held with the cold chain temperature records for at least 10 years.

Vaccination providers will need to be aware of any temperature breaches that might affect the expiry timeframes for any vaccine they are handling. Distributors must ensure they have a system in place for conveying that information to providers.

Equipment

Temperature monitoring

The following are the minimum requirements for monitoring freezers and refrigerators that store Comirnaty, outside the national store.

- A freezer/refrigerator maintenance plan (for example, requiring documented 6- to 12-monthly maintenance checks by the service provider)
- Two monitoring systems, run on two different sensors, in each freezer/refrigerator
- Daily minimum and maximum temperature recordings
- Continuous (24-hour-a-day) monitoring systems via either a datalogger or an external monitoring (eg, cloud-based) system that allows daily minimum and maximum recordings to be downloaded and reviewed weekly
- An external alarm system set to activate if temperatures go beyond the required range (-25ºC to -15ºC or -90ºC to -60ºC or +2ºC to +8ºC). (This system is a requirement for all distributors, including DHB pharmacies, and is strongly recommended for all providers who store Comirnaty vaccines)
- An appropriately documented and tested response process, back-up power supply and processes for alternative storage if the freezer/refrigerator malfunctions and cannot store the vaccine within the required temperature ranges. This will require the transfer of the vaccine:
  - from -70ºC to -20˚C or +2˚C to +8˚C
  - from -20ºC to +2˚C to +8˚C
  - from +2ºC to +8ºC to another+2ºC to +8ºC refrigerator or chilly bin(s) at +2ºC to +8ºC.

Providers must have these requirements in place and demonstrate how their processes work before they can achieve CCA/CCC.

Freezers -70ºC storage

There are a range of ultra-cold freezers available. Most **do not** have an internal fan to circulate air, so gaps between the vaccine boxes may not be required. However, how vaccines should be placed in these freezers will vary, depending on the freezer manufacturer's advice. Facilities with ultra-cold storage will need to supply the CCA assessor with information on the freezer manufacturer's requirements for their particular brand of freezer.

Freezers -20°C storage

Spark-free freezers have no fan within the chamber. Vaccines placed within a spark-free freezer do not need to have airflow gaps as the freezer uses the passive conductive properties of the vaccine within to achieve a stable temperature. Note that spark-free freezers have a much longer recovery time after a door opening, so users will need to be extra careful to avoid opening the door for too long or too often.

Fan-assisted freezers feature an internal fan to help circulate the air throughout the chamber. Fan-assisted freezers operate in a similar way to a standard vaccine refrigerator, just in a lower temperature range. Vaccines placed within a fan-assisted freezer must have the airflow gap placement as within a refrigerator; see section 7.1 of the **National Standards** and criteria 3 of the **CCA documentation**.

Fan-assisted freezers have a much faster temperature recovery time than spark-free freezers after a door opening.

Freezers used for Comirnaty storage must be pharmaceutical/laboratory grade freezers that are recommended by the freezer manufacturer/retailer for this purpose. Freezers must be installed and operated according to the freezer manufacturer's requirements and should be no more than 10 years old, as this is considered their lifespan under normal operation. Pharmaceutical/vaccine freezers, like refrigerators, should only be used in a temperature-controlled, well ventilated environment to allow the motor to stay sufficiently cool.

Refrigerator and transport – +2°C to +8°C

All refrigerators and vaccine transportation systems must comply with the requirements in the **National Standards**. In addition, the following apply to any transport of Comirnaty in the +2°C to +8°C system.

- As noted above, any refrigerator storing Comirnaty vaccines must have 24-hour-a-day monitoring, via either a datalogger or an external monitoring system (eg, cloud based). It is required for wholesalers and recommended for providers that the continuous monitoring system trigger an external alarm if temperatures go beyond the required range (+2°C to +8°C) and there is a documented process for following up alarms.
- Transporting Comirnaty requires a datalogger with external display as outlined in section 7.3 of the **National Standards**.

- Wholesalers transporting vaccines via courier must ensure that an appropriate datalogger is used in all transports. The datalogger must have a visible indicator to show on unpacking if the temperature remained in range during transport.
- Comirnaty vaccines must not be transported with only a digital minimum/maximum thermometer.

Before the first transport of Comirnaty all equipment and processes must be validated to demonstrate that temperatures will be maintained in the required +2°C to +8°C range for the expected full duration of transport.

Ambient air temperature monitoring

Before dilution, the Comirnaty vaccine must be brought to room temperature (not cold to touch). After dilution, the Comirnaty vaccine can be stored at room temperature for up to six hours; if it is returned to the refrigerator, it must be returned to room temperature before being used.

Comirnaty vaccine can diluted and drawn up and stored at room temperature (maximum of +30°C) in the vaccinators' area for up to six hours post dilution. For this reason, all providers must have a system in place for measuring and recording the ambient air temperature.

It is not acceptable to assume the room temperature or rely on air conditioning settings to keep the room temperature below 30°C. The room temperature must be actively monitored, for example, using an independent thermometer or datalogger.

This ambient air temperature information must be recorded and stored along with the other vaccine temperature recordings for at least 10 years.

Handling temperature breaches

Refer to the current version of the *Operating Guidelines for DHBs and Providers: COVID-19 Vaccine Immunisation Programme,* or its successor, for all temperature breaches for Comirnaty vaccine:

1. Temperature breaches that occur in transport between the national store and DHB pharmacies (and vaccinator sites) must be dealt with by the Ministry's COVID-19 logistics team.
2. For temperature breaches of Comirnaty stored at -70ºC or -20ºC, once the initial response has been completed (quarantining the vaccine in appropriate storage), contact either the IMAC COVID-19 immunisation advisor or the Ministry's COVID-19 logistics team for advice.
3. For +2ºC to +8ºC storage temperature breaches, follow the operating guidelines.

IMAC COVID-19 immunisation advisors

For cold chain advice, Monday to Friday 0830–1700 hours (8.30 am to 5 pm):

- Northern: Lisa Box **lisa.box@auckland.ac.nz**
- Midland: Olivia Haslam **Olivia.Haslam@auckland.ac.nz**
- Central: Melanie Miller **Melanie.Miller@auckland.ac.nz**
- Southern: Sue Rogers **Sue.Rogers@auckland.ac.nz**

For guidance, 1700–2000 hours (5 pm to 8 pm) weekdays and on weekends 0800–2000 hours (8 am to 8 pm):

- Phone: 0800 IMMUNE (0800 466 863).

The Immunisation Advisory Centre