

## Cold chain in community pharmacies: Frequency asked questions (FAQs)

These FAQs have been developed by the National Public Health Service to support cold chain management in community pharmacies offering immunisation services.

### ***Cold chain in community pharmacies general FAQs***

Question	Answer
What is cold chain management?	Cold chain management refers to the process of storing, transporting, and handling temperature-sensitive products, such as vaccines, under controlled conditions from the point of manufacture to the point of administration. Cold chain management includes maintaining and monitoring temperature conditions to ensure product integrity and effectiveness is preserved at all times.
Why is cold chain management important when providing immunisation services?	Effective cold chain management ensures that vaccines are consistently maintained within the recommended temperature range (usually +2°C to +8°C for most vaccines) at all times. This is critical because vaccines can lose their potency and effectiveness if exposed to temperatures outside their recommended range, which may result in a cold chain excursion or cold chain failure where revaccination would be required.  This factsheet covers essential information on cold chain: <a href="#">Essential Cold Chain information</a>
Do pharmacies need additional cold chain accreditation before offering immunisation services?	No, cold chain accreditation is already included as part of the licensing of a pharmacy, provided that the pharmacy is fully compliant with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2 <sup>nd</sup> edition). A pharmacy may only store vaccines and provide immunisation services if all requirements of the National Standards are met. Unless otherwise specified by the Medicines Control team, no additional cold chain assessment is required beyond compliance with these standards.
How are cold chain standards regulated in community pharmacies?	Cold chain management for pharmaceuticals and vaccines in pharmacies are regulated by Medsafe's Medicines Control team.
Who should I contact for support if I want to start offering offsite immunisation services?	Contact your <a href="#">local immunisation coordinators</a> to notify them of your intention to offer offsite immunisation services. There are different requirements in each region/ district. Some regions/ districts have additional sign-off requirements. To support your sign-off process and best practice, make sure you have the essential cold chain equipment and understand how to maintain and monitor cold chain for offsite services.  Here are some resources relating to offsite cold chain management:

	<ul style="list-style-type: none"> <li>• Appendix 2 of <a href="#">National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)</a></li> <li>• <a href="#">IMAC Vaccine Storage and Transportation course</a> (free online course)</li> <li>• <a href="#">Offsite vaccine storage and monitoring essentials</a></li> <li>• <a href="#">Off-site Immunisation Programme – Chilly Bin Log</a></li> <li>• <a href="#">Chilly bin packing protocol best-practice guidelines</a></li> <li>• <a href="#">Packing a chilly bin video</a></li> </ul>
<p>When should I contact my local Immunisation Coordinator?</p>	<p><a href="#">Local immunisation coordinators</a> support:</p> <ul style="list-style-type: none"> <li>• cold chain breaches (see next FAQ section), excursion, or failures</li> <li>• missing or incomplete temperature records,</li> <li>• clinical vaccination assessments,</li> <li>• emergency equipment,</li> <li>• spatial logging of pharmaceutical fridges holding vaccines,</li> <li>• offsite immunisation services (e.g. packing a vaccine chilly bin),</li> <li>• any other aspects of setting up an immunisation service.</li> </ul>
<p>What is the difference between a cold chain breach, cold chain excursion, and cold chain failure?</p>	<p><b>Cold chain breach:</b> An event that has led to vaccines being stored or transported in temperatures outside the required +2°C to +8°C range, without compromising the potency or stability of the vaccines.</p> <p><b>Cold chain excursion:</b> An event that has led to the vaccines being stored or transported in temperatures outside the required +2°C to +8°C range and, as a result, vaccines are compromised and need to be returned for destruction.</p> <p><b>Cold chain failure:</b> An event in which vaccines involved in a cold chain excursion are administered to patients, leaving them vulnerable and at risk of not being protected against the disease.</p> <p>For additional cold chain related terminologies and definitions, see the <a href="#">National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)</a>.</p>
<p>When do I need to contact my local immunisation coordinator to notify them of a temperature/ cold chain breach?</p>	<p>You need to contact your local immunisation coordinator if:</p> <ul style="list-style-type: none"> <li>• the vaccine refrigerator temperature went under +2°C.</li> <li>• the vaccine refrigerator temperature was between +8°C to +12°C, for more than 30 minutes.</li> </ul> <p><b>Note:</b> <i>the 30-minute window does not apply to temperature monitoring device with buffered probes.</i></p> <ul style="list-style-type: none"> <li>• the vaccine refrigerator temperature went over 12°C.</li> </ul> <p>Refer to the <a href="#">IMAC cold chain temperature breach flow chart</a>. It is standard practice for a pharmacy to also complete a Pharmacy Defence Associated (PDA) <a href="#">Incident Notification Form</a>, as well as any additional forms required for insurance claims.</p> <p>You may also be asked to complete the <a href="#">Cold chain breach or excursion form</a>.</p>

How can I escalate cold chain management concerns in the pharmacy I am working in?	Address your concerns with the pharmacy owner or the dispensary manager (or equivalent). If your concerns remain unresolved, you should contact your local immunisation coordinator and regional Pharmacy Portfolio Lead, who can support any escalation to Medicines Control, if required.
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### **National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition) related FAQs**

Question	Answer
How frequently do I need to record refrigerator temperatures and service the refrigerator?	<p>This is not an exhaustive list of activities.</p> <ul style="list-style-type: none"> <li>• Daily: <ul style="list-style-type: none"> <li>○ Minimum and maximum temperature preferable at the beginning of each operating day and document these temperatures on an <a href="#">Annual Cold Chain Management Record</a>.</li> <li>○ Any temperatures outside the +2°C to +8°C range <b>must</b> be investigated and the outcome documented in accordance with the pharmacy's incident reporting procedure, except when the temperature is between +8°C and +12°C for less than 30 minutes for known reasons (in this case, the breach must still be documented but no further action is required). <b>Note:</b> <i>the 30-minute window does not apply to temperature monitoring device with buffered probes.</i></li> </ul> </li> <li>• Weekly: <ul style="list-style-type: none"> <li>○ Download and save datalogger or continuous real-time temperature information. Review for any breaches.</li> <li>○ Review the temperature data to ensure the temperatures are within the required +2°C to +8°C and against the daily minimum/maximum temperature records for the same week, noting any breaches, compare for any differences, and taking appropriate action if any are identified.</li> </ul> </li> <li>• Annually: <ul style="list-style-type: none"> <li>○ Servicing of refrigerator - Arrange a service and maintenance check of the pharmaceutical-grade refrigerator by an appropriately qualified independent technician and according to manufacturer's recommendations.</li> <li>○ Review the pharmacy's cold chain policy and immunisation services standard operating procedures, ensuring all staff are familiar with and following the outlined processes.</li> <li>○ Complete a cold chain accreditation (CCA) self-assessment using the <a href="#">CCA Provider Self-Assessment Form</a> (recommended as best practice).</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• Frequency depending on your standard operating procedure (SOP): <ul style="list-style-type: none"> <li>◦ Temperature monitoring equipment validation (e.g. min/max, data logger – as recommended by manufacturer)</li> </ul> </li> </ul>
Does the daily minimum and maximum temperature recording and weekly datalogger download need to be completed by a pharmacist?	<p>No. This task can be assigned to other dispensary team members such as a pharmacy technician or an intern pharmacist. However, it is important that the person assigned these tasks understand the escalation process in the event of a temperature breach.</p> <p>Datalogger or online continuous real-time temperature monitoring service temperature data must be downloaded and reviewed weekly.</p>
Who is responsible for ensuing cold chain practice is compliant with National Standards?	The business owner, dispensary manager (or equivalent), and vaccinators are responsible to ensure cold chain practice and management is compliant with the National Standards.
What is the status of the National Standards review?	Health New Zealand   Te Whatu Ora is reviewing the <a href="#">National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition)</a> and the <a href="#">2021 COVID-19 Vaccine Addendum</a> . Updates will be communicated to the sector as soon as they are available.
Do pharmacies need a cold chain policy?	<p>All pharmacies providing immunisation services <b>must</b> have both a cold chain policy and an immunisation service standard operating procedure (SOP) in place. A designated cold chain lead, along with a back-up staff member, must be identified. All dispensary staff should be oriented to the cold chain policy and immunisation service SOP as part of their onboarding.</p> <p>Including your local immunisation coordinator's contact details in your cold chain policy is essential, as this supports effective incident management.</p> <p>A template is available here: <a href="#">Cold Chain policy template</a></p> <p>An orientation checklist is available here: <a href="#">Staff cold chain orientation guide/checklist</a></p>
Is the Cold Chain Accreditation (CCA) self-assessment compulsory?	While the <a href="#">CCA self-assessment form</a> is not a requirement, it is <b>strongly recommended</b> as best practice that you complete this annually. This is recommended to be completed well before the beginning of flu vaccination season to allow time for any issues arising to be addressed. This will provide additional assurance that your pharmacy is compliant with the National Standards, identify potential risks, and promote ongoing improvement. The CCA self-assessment may also be required as part of the Medicines Control audit or remedial plan if non-compliance is identified.
Who is responsible for ensuring the annual refrigerator	The pharmacy owner or the dispensary manager (or equivalent) is responsible for ensuring the refrigerator is serviced at least annually

maintenance check is completed?	by a trained technician. The results of the service <b>must</b> be documented.
Can I continue to use my refrigerator if it is older than 10 years?	<p>Pharmaceutical fridges used to store vaccines that are reaching 10 years old can continue to be used, provided that continuous real-time temperature monitoring services with out-of-hours alarming and notification processes are in place and cold chain storage is compliant with the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition). Your local immunisation coordinator can confirm if your fridge is eligible.</p> <p>Refer to: <a href="#">Interim Statement on Lifespan of pharmaceutical fridges for vaccine storage</a> and related <a href="#">FAQs</a>.</p>
What is the difference between a “continuous real-time temperature monitoring service” and a “datalogger”?	<p><b>Continuous real-time temperature monitoring service:</b> also called cloud-based monitoring, web-based monitoring, external monitoring or real-time monitoring. Such services send temperature information from a sensor in a provider’s refrigerator to software that can be viewed through a website. They may be in-built or separate, like a datalogger; records must be downloaded/accessed and reviewed weekly.</p> <p><b>Datalogger:</b> an electronic device that measures the current refrigerator temperature at preset intervals and records information that can then be downloaded/ accessed and reviewed weekly. Datalogger is used as the generic term for all devices that sample and store/transmit temperatures from within the refrigerator.</p>
What is spatial logging?	Cold chain spatial logging is when multiple sensors are placed in different locations within the refrigerator to identify temperature variations to create a spatial temperature profile. This helps identify warmer and cooler spots within the refrigerator.
Who is responsible to spatially log my vaccine refrigerator and how frequently does this occur?	Spatial logging of refrigerator is undertaken by your local Immunisation Coordinator, at least once every three years.
Where can I get additional cold chain resources to support my pharmacy team with cold chain compliance?	<p>Here are links to key websites that you may find useful:</p> <ul style="list-style-type: none"> <li>• <a href="#">Health NZ Cold Chain website</a></li> <li>• <a href="#">IMAC Cold Chain website</a></li> </ul>