

FAQs on Vaccine Cold Chain Compliance for Community Pharmacies

To: Community Pharmacies offering vaccination services

From 1 February 2018, cold chain management in pharmacies will be regulated as part of the pharmacy licensing framework administered by Medicines Control. This fact sheet outlines the changes.

All immunisation providers including community pharmacies must meet the requirements in the *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* (the Standards). The Standards and other cold chain documents can be found on the Ministry of Health (the Ministry) website at www.health.govt.nz/coldchain

Community pharmacies who are offering or who plan to offer vaccination services are responsible for complying with **all** requirements within the Standards (including appropriate equipment, monitoring, recording, and policies and procedures).

Immunisation Coordinators will continue to provide community pharmacies with:

- cold chain advice (e.g. when purchasing new cold chain equipment)
- assistance with cold chain breaches or failures
- clinical assessments for pharmacists who have completed their vaccination training course
- three yearly spatial logging of pharmaceutical refrigerators.

Background

Medicines Control regulates the pharmaceutical supply chain, including community pharmacies.

Pharmacies are issued with a Licence to Operate Pharmacy (Licence) in accordance with the Medicines Act 1981, and are required to have and maintain appropriate equipment necessary to provide pharmacy services (including vaccination services).

In 2017, the Ministry published the Standards, which outline the cold chain management requirements that all immunisation providers, (including community pharmacies) must meet if they provide a vaccination service.

The process of assessing a provider's compliance with the Standards is called Cold Chain Accreditation (CCA) and this has traditionally been undertaken by the local immunisation/cold chain coordinators (Coordinators) in each District Health Board area.

What are the changes from 1 February 2018?

CCA will no longer be issued to community pharmacies by Coordinators. By holding a Licence to Operate Pharmacy, pharmacies providing vaccination services will be deemed to hold current CCA.

What has changed about the assessment of community pharmacy cold chain management requirements?

By holding a Licence to Operate Pharmacy and providing vaccination services, a pharmacy is required to meet **all** the requirements for vaccine storage and transportation. CCA will no longer be performed by Coordinators, as advised by Medicines Control in January 2018.

Compliance with the Standards (for pharmacies providing vaccination services) will be reviewed during audits conducted by Medicines Control.

Coordinators will continue with their role of support and education for pharmacies delivering or planning to deliver a vaccination service, and it is important to maintain these relationships.

What do pharmacies intending to provide vaccination services need to do?

There are two requirements that must be met before a pharmacy can provide vaccination services:

- 1) The pharmacy must meet all the requirements specified in the Standards (including all equipment and monitoring requirements), **and**
- 2) There must be a fully trained pharmacist vaccinator (or authorised vaccinator) holding current certification to provide the service at the pharmacy.

What are the requirements to become a Pharmacist Vaccinator?

A pharmacist must:

- complete the vaccinator training course; and
- pass a clinical assessment conducted by their Coordinator; and
- complete a CPR level 4 training course
- notify the Pharmaceutical Society of New Zealand (Society) when they fully qualify as a pharmacist vaccinator; and
- maintain their status as a pharmacist vaccinator by completing an immunisation update course every two years, maintaining their CPR certification and advising the Society that these requirements have been met.

For more information refer to Appendix 4 in the *Immunisation Handbook 2017* at www.health.govt.nz/publication/immunisation-handbook-2017

For new pharmacist vaccinators, the Coordinator will carry out a basic cold chain review at the pharmacy as part of the clinical assessment. If the requirements of the Standards are not met, the Coordinator will cease the assessment and ask Medicines Control to follow up with the pharmacy. No vaccinations can be provided until the identified issues are appropriately resolved.

What happens if a pharmacy has a cold chain breach or failure?

A cold chain breach is an event that has led to the vaccines (and other temperature controlled medicines) being stored or transported outside the required +2°C to +8°C range, and a cold chain failure is when these vaccines are compromised and administered to patients.

When vaccines are involved in a cold chain breach please label and quarantine the vaccines in your refrigerator and contact your Coordinator for advice. For more information refer to the Standards.

What are the annual checking requirements for pharmaceutical refrigerators?

All equipment used for storing, transporting and monitoring vaccines must be fit for purpose and appropriately maintained and tested.

It is the pharmacy's responsibility to arrange for an annual service of their pharmaceutical refrigerators by an appropriately qualified independent technician (e.g. a service technician from the refrigerator company), and the results of the check must be documented. Validation of the temperature monitoring devices (inbuilt minimum/maximum thermometer and data logger) must be undertaken as part of this check.

How is the three yearly spatial logging of pharmaceutical refrigerators conducted?

The Coordinators conduct spatial logging of pharmaceutical refrigerators every three years. This logging maps warmer and cooler spots in the refrigerator. The Coordinator will send the results/recommendations to the Pharmacy for action if required.

Can pharmacies conduct a cold chain self-assessment?

Yes, the Ministry's CCA self-assessment form can be used to assess your cold chain management practices against the Standard's requirements. A copy of the form can be found at: www.health.govt.nz/coldchain

Are other training resources available?

A free online vaccine storage and transportation course is available on the Immunisation Advisory Centre (IMAC) website at: www.immune.org.nz/health-professionals/education-training

The course is beneficial for new and existing pharmacist vaccinators and takes about an hour to complete. You will need to create an account and login to be able to access the course. You may also be able to use this course as Group 2 points for your ENHANCE CPD requirements.

A short cold chain video is also available at www.immune.org.nz/health-professionals/cold-chain

Further questions

For more information about your cold chain compliance contact Medicines Control at medicinescontrol@moh.govt.nz