

FAQs for immunisation coordinators on Vaccine Cold Chain Compliance for Community Pharmacies

To: Immunisation Coordinators providing cold chain advice and support to community pharmacies

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

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.

What has changed from 1 February 2018?

Cold Chain Accreditation (CCA) will no longer be issued to community pharmacies by immunisation coordinators (Coordinators). By holding a Licence to Operate Pharmacy, pharmacies providing vaccination services will be deemed to hold current CCA.

What has changed for Coordinators in the assessment of vaccine cold chain management of community pharmacies?

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.

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 they purchase 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 the pharmacy's pharmaceutical refrigerator(s).

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 if a new or existing vaccinating pharmacy calls me and asks for a CCA review?

Advise the pharmacy you are no longer responsible for undertaking their CCA review.

It is important to remind pharmacies they:

- must continue to meet all of the Standards' requirements and
- will be expected as part of their Licence to produce evidence of their previous CCA reviews (if undertaken prior to 1 February 2018), vaccinator training and update certificates at their next audit by Medicines Control.

What do I do if I have any concerns about the pharmacy's cold chain management or their equipment e.g. during a clinical assessment?

If, during a clinical assessment (or at any time) you are concerned about a pharmacy's cold chain management please advise the charge pharmacist you will be stopping the assessment and informing Medicines Control.

A communication template is being developed to assist you in reporting your concerns with a pharmacy's cold chain management to Medicines Control. A copy of the template will be available at www.health.govt.nz/coldchain and can be emailed to Medicines Control once completed.

Medicines Control will use the template to assess the pharmacy's cold chain management and may take regulatory actions as required.

It is the pharmacy's responsibility to undertake any corrective actions, as the Coordinator you may be able to provide advice on these actions.

Once their cold chain management has been reviewed by Medicines Control and they have met the Standards' requirements, the pharmacist may contact you again to complete the clinical assessment.

What happens if a pharmacy contacts me to report a cold chain excursion, breach or failure?

Follow the Standards' cold chain excursion flow chart procedure, and advise the Medicines Control team via email using the communication template.

What is my role in annual logging of the pharmacy's pharmaceutical fridge(s)?

The Standards require that annually a calibrated logger is placed alongside the daily temperature monitoring probe for a minimum of 24 hours.

It is the pharmacy's responsibility to ensure the annual logging check occurs.

If you have sufficient resources to continue to undertake the annual temperature check for vaccinating pharmacies in your area, please let the pharmacies know that you can continue to offer this service. Alternatively, the pharmacy may have a contract for this service as part of their annual refrigerator maintenance service.

What is my role in three yearly spatial logging of a pharmacy's pharmaceutical refrigerator(s)?

The Standards require that every three years spatial logging of pharmaceutical refrigerator(s) is undertaken using three calibrated loggers.

Undertaking spatial logging on a pharmacy's pharmaceutical refrigerator(s) remains with the coordinator. The rationale for leaving this role with the coordinator is to provide a natural point of contact between the pharmacy and their local coordinator to maintain an ongoing relationship.

The results (and recommendations if required) of the spatial logging should be emailed to the pharmacy. Where non-compliance is identified this must be notified to Medicines Control using the communication template.

How will I know if a pharmacy is under investigation for not meeting the Standards' requirements or has a restriction on their License related to refrigerated medicines?

When contacting a pharmacist to arrange a clinical assessment we recommend you ask them if their pharmacy is compliant with the Standards' requirements. IMAC has a check list available for pharmacies to assess if they meet the minimum requirements so you can refer them to this document.

If a pharmacy has a restriction on their Licence related to refrigerated medicines (including vaccines) they will have been advised by Medicines Control that this relates to any vaccination service they run or would like to run.

How do I contact Medicines Control?

Medicines Control can be contacted by email at medicinescontrol@moh.govt.nz

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A copy of these FAQs can be found at www.health.govt.nz/coldchain