TARANAKI DISTRICT HEALTH BOARD

IMMUNISATION PROVIDER COLD CHAIN NON-COMPLIANCE POLICY

RATIONALE:
The National Standards for Vaccine Storage and Transportation for Immunisation Providers in New Zealand[1] outlines the requirements for providers to achieve the standards. The aim is to safely store and transport vaccines in order to improve the health of New Zealanders by protecting them from vaccine preventable diseases through an effective immunisation programme. The standards were reviewed and updated in 2019.

All DHBs must have a Cold Chain Non-Compliance Policy; which documents the local process for addressing provider cold chain non-compliance. Each DHB must review this process annually and make the documentation available to the Ministry on request.

PURPOSE:
To describe the process in Taranaki when an Immunisation Provider fails to meet the requirements or is found to be noncompliant of the National Standards.

STANDARD:
All immunisation providers are required to meet all the National Standards for Vaccine Storage and Transportation for Immunisation Providers – see Appendix One.

SCOPE:
All immunisation providers in Taranaki. Immunisation providers are defined as: *any provider storing and/or administering vaccines to individuals in New Zealand. Examples include but are not limited to: general practices, public health units, community pharmacies, corrections facilities, outreach immunisation services, travel clinics, emergency medical services, public and private hospital wards and departments/pharmacies, and occupational health services.*[1]

DEFINITIONS:

CCA	Cold Chain Accreditation
Compliance Committee	Members include representatives from the DHB, PHO, IMAC, the Medical Officer of Health and the Immunisation Coordinator
DHB	District Health Board
IMAC	Immunisation Advisory Centre
Medicines Control	Regulatory team within Medsafe at the Ministry of Health
MOoH	Medical Officer of Health
P&F	Planning and Funding portfolio manager
PHO	Primary Health Organisation
Reviewer	Immunisation/cold chain coordinator

[1] Ministry of Health. 2019. National Standards for Vaccine Storage and Transportation for Immunisation Providers (2nd edition). Wellington: Ministry of Health.

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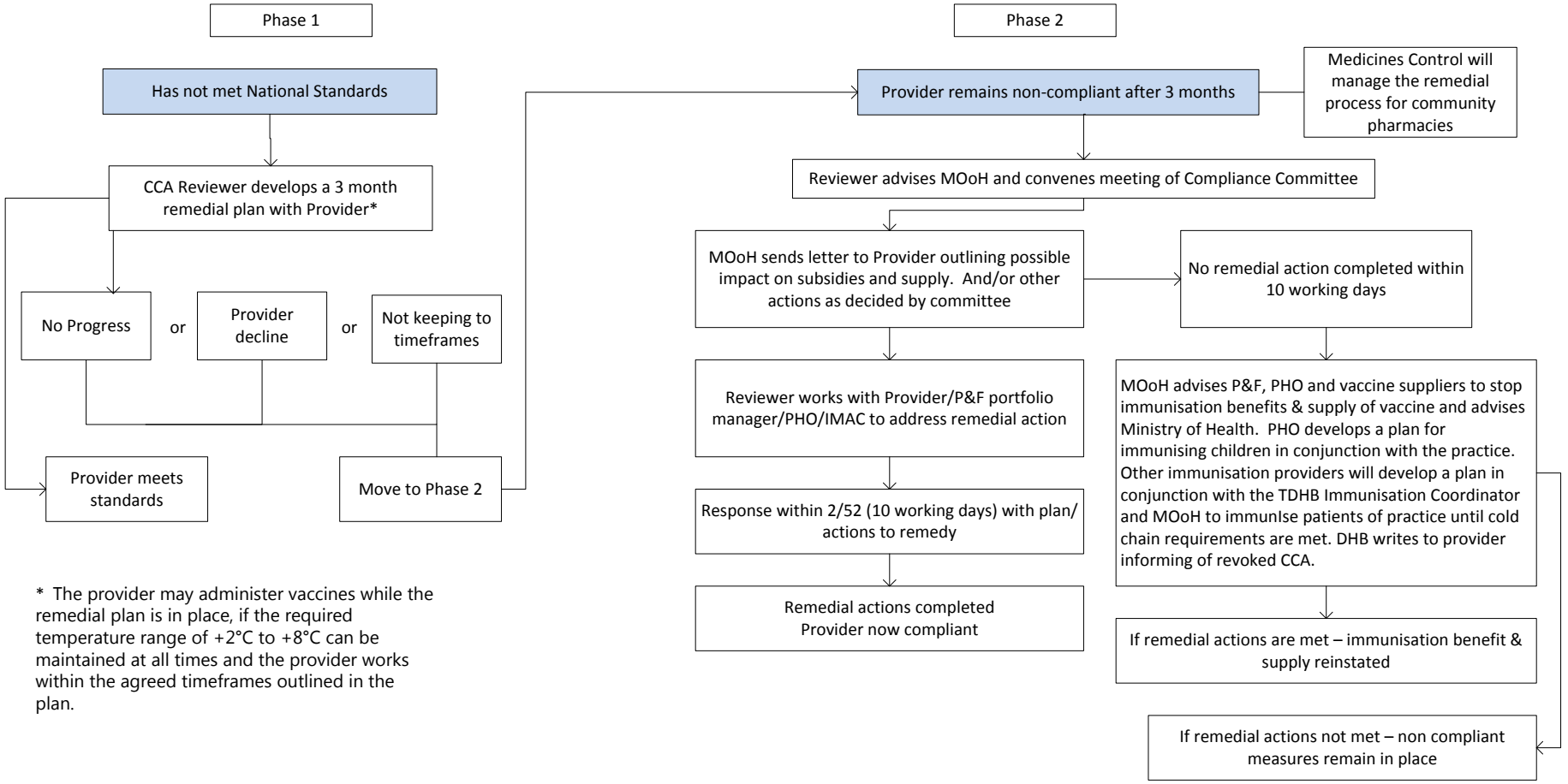
Algorithm Of Immunisation Provider Cold Chain Non-Compliance



* The provider may administer vaccines while the remedial plan is in place, if the required temperature range of +2°C to +8°C can be maintained at all times and the provider works within the agreed timeframes outlined in the plan.

APPENDIX ONE

National Standards for Vaccine Storage and Transportation for Immunisation Providers[1]:

1. All immunisation providers must hold cold chain accreditation or cold chain compliance before offering immunisation services.
2. All clinical staff must ensure continuity of the cold chain. They must also:

- be competent in all aspects of vaccine storage and transportation to ensure that vaccines are kept within the required +2°C to +8°C temperature range at all times
- take appropriate action when the cold chain is not maintained
- take responsibility for ensuring that the vaccines they administer have been correctly stored
- have read and understood, and comply with, the provider's cold chain policy.

3. All immunisation providers must have a cold chain policy containing the required information outlined in section 6.1. The Ministry of Health has provided a cold chain policy template that providers can adapt and use for their facility (see www.health.govt.nz/coldchain).
4. All immunisation providers must have a stock management process that ensures they are not over- or under-stocked.
5. All immunisation providers must use one or more pharmaceutical refrigerators for vaccine storage that:

- stores only medicines and vaccines
- is appropriately maintained and serviced
- contains only vaccines and medicines stored in their original packaging and properly spaced within the pharmaceutical refrigerator.

6. All immunisation providers must have two systems for monitoring the temperature that vaccines are being stored at:

- a daily check device that records the minimum and maximum temperatures reached – for example, an inbuilt refrigerator monitor or digital minimum/maximum thermometer
- a weekly check device that records the temperature at least every 10 minutes – for example, a datalogger. Every week the provider must then download/ access and review this information against other temperature recordings taken, take appropriate action and store the week's information.

7. All providers must have a cold chain process and equipment for ensuring safe temporary storage of vaccines if a power outage occurs or a refrigerator fails.
8. All equipment used for storing, transporting and monitoring vaccines must be fit for the purpose, and appropriately maintained and tested. As part of this maintenance and testing, providers must:

- arrange for annual servicing of pharmaceutical refrigerators
- trial and test the capacity of their portable storage equipment
- ensure that spatial logging of pharmaceutical refrigerators occurs at least every three years.

9. All documentation associated with vaccine temperature monitoring must be kept for at least 10 years. This includes:

- daily minimum and maximum temperature recordings
- weekly datalogger downloads or records
- temperature recordings from vaccines transported and stored in chilly bins
- actions taken when a cold chain breach, excursion or failure occurs.

10. All immunisation providers who offer offsite immunisation clinics – for example, occupational health, school-based immunisation programmes and outreach immunisation services – must have appropriate, tested equipment for this purpose. Note: this situation is different from that involving temporary storage or transport following a power outage or refrigerator failure.

APPENDIX TWO

Roles

	Immunisation Coordinator	DHB	PHO	Medical Officer of Health	IMAC Regional Immunisation Advisor
Routine	✓	-	-	-	-
On Remedial Plan	✓	Informed of progress	Plan to support practice to achieve compliance	Informed and input to remedial plan	Informed and input to remedial plan (as appropriate)
Revoke	Ensure vaccines removed & works with provider to re-gain CCA	Communications plan for event	Develop plan to provide alternative sites for national schedule vaccines and communication advice (as appropriate)	Part of review, informs provider & Ministry of Health of Compliance Committee decision	Part of review & Advisor