

National Guidelines for Vaccine Storage and Distribution

2012

Developed on behalf of the Ministry of Health by Immunisation Advisory Centre (IMAC) University of Auckland

Citation: Ministry of Health. 2012. *National Guidelines for Vaccine Storage and Distribution*. Wellington: Ministry of Health.

Published in September 2012 by the Ministry of Health PO Box 5013, Wellington 6145, New Zealand

> ISBN 978-0-478-39389-7 (online) HP 5564

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Introduction

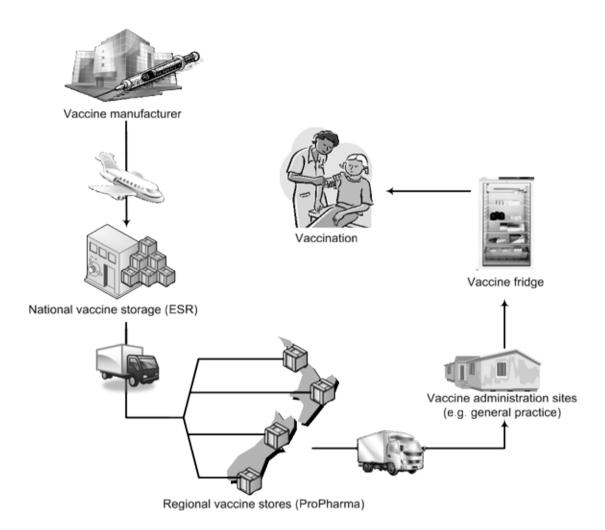
These guidelines are intended to guide practice, and to ensure that vaccines delivered within New Zealand have been stored correctly to maximise their effectiveness. The guidelines supersede the *Vaccine Storage and Distribution National Standards 2002* and supplement the cold chain policy in the *Immunisation Handbook 2011*.

The success of an immunisation programme depends on a system that ensures that vaccines are not thermally damaged (by heat or freezing) during transport and storage.

The system of transporting and storing vaccines within the recommended temperature range of +2°C to +8°C from the place of their manufacture to the point of vaccine administration is called the 'cold chain'.

The integrity of the cold chain is dependent not only on the equipment used, but also the people involved and the practices they undertake.

Figure 1: The different stages of the cold chain



Everyone who handles vaccines is responsible for maintaining standards that will ensure vaccine potency at each stage of the cold chain.

The cold chain

The 'cold chain' is defined in the Ministry of Health *Immunisation Handbook 2011* as 'the system of transporting and storing vaccines at +2°C to +8°C from the place of manufacture to the point of vaccine administration (the individual)'. The *Handbook* has a comprehensive section on the cold chain and vaccine storage.

Vaccines can become less effective or destroyed if they are:

- frozen
- allowed to get too hot (repeated exposures have cumulative effect)
- exposed to direct sunlight or fluorescent light.

The impact of thermal damage (heat or freezing) on vaccine potency is complex, and our knowledge of it is based on limited human data. Impact varies for each vaccine. Once a vaccine has been thermally damaged, its loss of potency cannot be reversed (*Immunisation Handbook 2011*).

Freezing is the most common reason for vaccine damage and wastage in New Zealand.

The following vaccines are freeze-sensitive:

- diphtheria, tetanus and acellular pertussis containing vaccines
- hepatitis B
- Haemophilus influenzae type b (Hib)
- inactivated polio (IPV)
- any combinations of the above
- meningococcal
- pneumococcal
- influenza
- human papillomavirus (HPV)
- rotavirus
- vaccine diluents.

All vaccines are heat-sensitive, but the most heat-sensitive are:

- measles-mumps-rubella (MMR)
- IPV
- Bacille Calmette-Guérin (BCG)
- varicella.

MMR, BCG and varicella become even more heat sensitive when reconstituted. They are also light sensitive. Other vaccines that are light sensitive are:

- HPV
- · Infanrix-hexa
- ADT Booster.

The two essential elements of the cold chain system are:
the people managing vaccine manufacture, storage and distribution and those working in clinical practice
the equipment used for storing, transporting and monitoring vaccines between delivery of the vaccine to an immunisation provider and administration to a patient.

Arrival of vaccines in New Zealand

All National Immunisation Schedule vaccines used in New Zealand are manufactured overseas and delivered to the National Vaccine Store (NVS) situated at the Institute of Environmental Science and Research Ltd (ESR) in Wellington, where they must pass quality controls before being stored. When required, vaccines are distributed to the ProPharma regional stores in Whangarei, Auckland, Hamilton, Wellington, Christchurch and Dunedin and from there to local immunisation providers, including: primary care and public health providers, district health boards and prisons. The exception to this process is the seasonal influenza vaccines, which are stored and distributed by Healthcare Logistics (on behalf of the manufacturers) and then distributed directly to immunisation providers.

All vaccines are shipped by air to New Zealand in such a way that they remain at their recommended storage temperature for the entire journey. Some vaccine manufacturers may hold national stocks of high use vaccines to minimise possible supply disruptions.

All specifications for the shipment of vaccines to New Zealand are included in contracts for the supply of vaccines.

Before sending vaccines to the NVS, manufacturers must advise the NVS logistic officer of shipment details including the date the shipment is due to arrive at the NVS and the name and details of the delivery agent.

Cold chain loggers indicating whether the recommended storage temperature has been maintained during transport from point of manufacture to delivery at the NVS are included in all vaccine shipments. The loggers are carefully placed in the container, in the areas likely to experience the greatest temperature extremes, for example the coldest and hottest areas.

The shippers are clearly labelled to indicate the temperature sensitivity of their contents. The labelling indicates the temperature the vaccine is to be kept at during storage in transit.

Each container must contain a logger to detect temperatures above 8°C, and, if the vaccine is freeze-sensitive, a logger to detect temperatures below o°C. The NVS warehouse staff read data from the temperature loggers at the time of receipt to ensure that correct temperatures have been maintained throughout transportation to the NVS.

Any vaccine shipments or part-shipments that have been affected by a cold chain failure or have not been adequately monitored will be quarantined by the NVS, and maybe rejected if vaccine potency has been adversely affected.

National guidelines

National vaccine store responsibilities

The NVS manages the National Immunisation Schedule vaccine supply on behalf of PHARMAC. The NVS is responsible for all vaccines from their arrival at the store until their delivery to the ProPharma regional stores.

The NVS orders all National Immunisation Schedule vaccines in New Zealand (except those for influenza).

It is responsible for providing advice to PHARMAC, the Ministry of Health, regional distributors, immunisation coordinators, healthcare providers, and other agencies on request about vaccines and the cold chain (for example in regards to supplies and levels of thermal damage).

The NVS is also responsible for managing the National Cold Chain Audit (NCCA) process and the data it collects.

The NVS manages vaccine stock to ensure wastage is minimised and vaccines are maintained at the recommended temperatures during storage and transportation to the ProPharma regional stores.

It records all batch numbers, expiry dates and the particular ProPharma regional stores vaccines are dispatched to. It provides information on batch numbers to the regional stores and the Centre for Adverse Reactions Monitoring (CARM), and advises the regional stores of:

- vaccines available including brands, presentations and pack sizes
- the procedure for ordering vaccines from the NVS
- the turnaround time for orders
- any changes in regards to these matters.

The NVS staff are fully trained in the cold chain and procedures to manage cold chain excursions.

The NVS uses a medical waste facility in which vaccines are heat-sterilised to render them inactive, then crushed and buried in a sterile landfill as per requirements under the Resource Management Act 1991.

National Cold Chain Audit

PHARMAC and the Ministry of Health commission the National Cold Chain Audit (NCCA) to monitor National Immunisation Schedule vaccines. The audit monitors the cold chain of vaccines from their origin at the NVS until immunisation providers have administered all doses in the vaccine box.

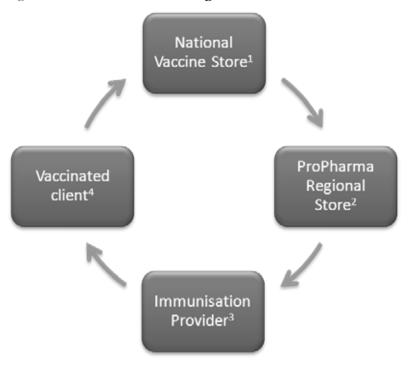
Note: Since publication of the *Immunisation Handbook 2011* the NCCA heat and freeze indicators have been replaced by a single digital monitor; accordingly, the NCCA record card has been changed to allow for documentation of readings from this new monitor. See Appendix 1 for further information.

A digital monitor (TagAlert) and record card is attached to a proportion of all National Immunisation Schedule vaccine packs (except those for influenza) prior to distribution. The digital monitor records temperatures every five minutes and produces a visible alarm if temperatures fall outside of the +2°C to +8°C range. See Appendix 1 for more information on the visible alarms and the appropriate course of action.

Vaccine boxes containing these monitors and cards are marked with a bright yellow sticker for ease of identification. On unpacking, the monitor and card must remain with the vaccines they arrive with until all the vaccines in the box have been used. Those handling the vaccines from this point must note the display on the digital monitor and document it on the record card. The monitor should be noted and the reading documented when each vaccine dose is used, and if a visible alarm is seen the alert number must be recorded on the record card and the local immunisation coordinator contacted immediately.

When the last vaccine dose has been used, the immunisation provider must read the monitor again, and document the reading on the record card. They must then return the digital monitor and the record card in the envelope provided to the NVS (see Appendix 6 for contact details).

Figure 2: The flow of NCCA digital monitor and record cards between providers



- 1 NVS staff insert the digital monitors and record cards in the National Immunisation Schedule vaccine boxes, activating the digital monitor when the vaccines are distributed to the ProPharma regional stores. The digital monitor reads 'OK'.
- The ProPharma regional store reads the digital monitor and documents the reading on the record card on arrival and on distribution of the vaccines to immunisation providers.
- 3 The immunisation provider reads the digital monitor and documents the reading on the record card on arrival of the vaccines at the practice/clinic and before each dose is administered.
- When the last of the vaccines is used, the immunisation provider again reads the digital monitor and completes the record card, then returns them to the NVS.

The digital monitor must be checked and the reading documented on the record card at each stage (details of the reading must be clearly legible: ideally in capitals or by way of a practice stamp).

Receipt and storage at the National Vaccine Store

The NVS' standard operating procedures specify procedures for the receipt and storage of vaccines.

All vaccines are unpacked and refrigerated immediately on delivery. They are placed in quarantine until staff have reviewed data from temperature loggers, vaccine specifications and quality control processes. This process is known as vaccine clearance.

Once the NVS manager has approved release of the vaccine it is available for supply to ProPharma regional stores.

Refrigerators that National Immunisation Schedule vaccines are stored in at the NVS are maintained as follows:

- Automated systems continuously monitor and record minimum and maximum temperatures.
- Staff monitor and record minimum and maximum temperatures every four hours in a temperature log. An alarm system is in place, linked to a 24-hour response service. If temperatures are consistently more than 2°C below or above 8°C, staff call an engineer to check the system and make an adjustments.
- The NVS has a contractual arrangement with a refrigeration service company to provide a 24-hour callout service, with a maximum response time of one hour.
- If the temperature falls below 2°C or exceeds 8°C, staff take immediate action. They advise the NVS manager, who decides whether vaccine potency has been compromised.
- Back-up power, refrigeration and air-circulation systems are in place.
- Staff implement a regular programme of maintenance, calibration of temperaturemeasuring devices and checks of back-up and alarm systems.

Transport between the NVS and ProPharma regional stores

The NVS' standard operating procedures include procedures for the transport of vaccines between the NVS and ProPharma regional stores.

Vaccines are packed as quickly as possible, and large quantities of vaccine do not remain unrefrigerated while awaiting packaging.

Containers used to transport vaccine are capable of keeping vaccine cool for a minimum of 72 hours. When a transport container is packed with more than one type of vaccine, the relative heat and freeze-sensitivities of the different vaccines are taken into account in the placement of vaccines relative to icepacks.

Icepacks are separated from vaccines with sufficient polystyrene sheeting or approved insulating matting to insulate the vaccine against freezing.

Two temperature data loggers are packed with each transport container sent to the ProPharma regional stores. The loggers record the temperature every minute and are accurate to 0.5°C. The digital recorders are checked for alarms at the ProPharma regional store. All digital recorders are sent back to the NVS for analysis.

Specifications as to the conditions in which vaccines must be stored, (in particular, temperatures and maximum transit time) are included in the service agreement with the courier company transporting the vaccines. Time frames for delivery are also agreed on.

The NCCA digital monitors are activated before the vaccines are packed. The monitors and record cards are placed in the loads likely to experience the warmest and coldest temperatures. The monitors and record cards stay with the vaccines that they were originally received with.

Healthcare Logistics' responsibilities

Healthcare Logistics manages the seasonal influenza vaccine supply on behalf of the manufacturers who hold the PHARMAC contract and also the distribution of privately funded vaccines on behalf of the manufacturers. Healthcare Logistics is responsible for storing these vaccines between arrival at the store and their delivery to immunisation providers.

Healthcare Logistics:

- stores vaccines to the manufacturer's specifications (including recommended storage temperatures)
- records all vaccine batch numbers, expiry dates and the immunisation providers the vaccines have been dispatched to
- advises immunisation providers of the vaccines available from their store, how to order them and the turnaround time for orders
- advises immunisation providers on any changes in vaccine presentations if requested by the vaccine manufacturers.

Healthcare Logistics staff are fully trained in the cold chain and the procedures to manage cold chain excursions.

Providers should return all unused seasonal influenza vaccine to Healthcare Logistics for secure destruction.

If there is a faulty product or there has been a cold chain failure involving the seasonal influenza or private vaccines supplied by Healthcare Logistics, providers should contact Healthcare Logistics on o9 969 0736 before disposing of them.

Regional guidelines

ProPharma regional stores' responsibilities

The ProPharma regional stores:

- maintain vaccines in good condition (and not thermally damaged) between receipt from the NVS and delivery to the immunisation provider
- manage and rotate vaccine stock
- maintain records of vaccine receipts and issues, including batch numbers, expiry
 dates and the status of NCCA digital monitors and record cards and data loggers as
 well as any incidents and returns
- communicate with immunisation providers regarding ordering procedures and delivery schedules, and ensuring that the time of transportation from the store to the provider meets contractually specified time limits
- assists in communicating any changes to vaccine brands, presentation or delivery systems to immunisation providers if requested by the Ministry of Health, PHARMAC or the NVS
- maintain documented protocols for the receipt, storage and distribution of vaccines and the management of consignments that fall outside specifications, and demonstrate adherence to the protocols in documentation
- notify the Immunisation Advisory Centre (IMAC) regional immunisation advisor of the immunisation providers that have been sent NCCA digital monitors and record cards with their vaccine orders
- notify the IMAC regional immunisation advisor of vaccines received for destruction.

IMAC is contracted by the Ministry of Health to undertake an annual cold chain audit of the ProPharma regional stores. The regional immunisation advisor usually completes this audit.

The regional stores accept compromised or damaged vaccines returned from providers and disposes of them using the methods described in the section titled NVS responsibilities.

Receipt and storage at the ProPharma regional stores

Written procedures for the receipt and storage of vaccines are included in the ProPharma regional stores standard operating procedures. Procedures must be in place to protect against cold chain failure, 24 hours a day and seven days a week.

The following guidelines apply to the regional stores' cool units:

- the unit is of sufficient size to store vaccines without exceeding 50 percent of the unit's storage capacity
- the unit may be purpose built or commercially manufactured
- the unit is located internally within the premises/building
- the unit door should have a heavy-duty latch-type fastening, or, if reliant on a vacuum seal only should be secured with a locking mechanism
- the room that houses the cool unit should be of sufficient size for the volume of vaccine to be stored and must be ventilated, as the efficiency of refrigeration equipment declines with high ambient temperatures
- the condenser of the unit should be installed and operated in line with the manufacturer's recommendations, to ensure sufficient ventilation
- the unit should be permanently wired into the wall outlet, to overcome the risk of deliberate or accidental disconnection
- the unit is equipped with a data logger device, capable of continuous temperature monitoring
- an automatic alarm system is fitted to the cool unit that will alert staff whenever the temperature of the unit is outside the safe limits
- the unit should contain at least two temperature sensors (depending on the size of the unit), located in a position to ensure the most accurate overall temperature control
- the unit temperature display is checked each day at the beginning of each working day and immediately prior to the end of the working day, and the minimum and maximum temperatures recorded in a temperature log
- a standby refrigeration system or electricity supply is available in the event of mechanical failure or power failure
- a regular programme of maintenance is in place, including calibration of temperature-measuring devices (by an accredited service provider) and checks of back-up and alarm systems
- the unit should be defrosted when ice greater than 1 cm thick builds up on the ice plate(s), or at six-monthly intervals.

All vaccines must be unpacked and refrigerated immediately upon delivery.

Any NCCA digital monitors and record cards attached to vaccines received from the NVS must remain attached to these vaccines. The digital monitor reading must be noted and recorded on the card when the vaccine is unpacked and monitored regularly during storage.

Vaccines are not stacked so high as to impede the flow of air in the cool unit.

All vaccines (and their diluents if applicable) should be stored in an orderly manner with the expiry date within easy view.

Vaccines are distributed using a lot control system (that is, short-dated vaccines are dispatched first). Immunisation providers are informed when a vaccine has a short expiry date so they can manage their vaccine orders and minimise vaccine wastage.

In the event of cold chain failures where vaccines have been compromised or recurrent episodes where temperatures fluctuate outside of +2°C to +8°C, the regional store must notify the Ministry of Health, PHARMAC, the NVS and regional immunisation advisor. Regional stores must also record any abnormal events (for example alarm activation) in their own maintenance logs.

Transport between the ProPharma regional stores and local immunisation providers

Immediately prior to dispatch from the regional stores, vaccines must be selected and then packed on a designated bench near to the cool unit.

NCCA digital monitors and record cards stored with vaccines must be included with the vaccines when they are sent to the provider. The digital monitor is read and the reading documented on the record card before the vaccines are packed. The digital monitors and record cards should be placed between the boxes of vaccines. They stay with the vaccines that they were originally received with.

Vaccines to be distributed should be packed in an appropriate-sized transport container alongside enough icepacks to ensure vaccines remain between +2°C to +8°C throughout their journey. The container's lid should be taped in place, along with a 'refrigerate, do not freeze' label with the date and time the vaccines were packed.

The courier or delivery agent collects and distributes vaccine orders to providers, all vaccines must be packed in such a way that the recommended temperature range of +2°C to +8°C is maintained at all times.

An audit of the effectiveness of the vaccine transportation method should occur on a minimum six-monthly basis using a data logger device. Regional stores should carry out such audits in summer and winter.

Local guidelines

Cold Chain Accreditation

Cold Chain Accreditation (CCA) is a tool immunisation providers use to support their cold chain management practices (*Immunisation Handbook 2011*). CCA is demonstrated through a provider assessment followed by review by an approved CCA reviewer (for example an immunisation coordinator). All immunisation providers, including public health services, emergency medical services and emergency departments of hospitals must be accredited. Based on the reviewer's findings, CCA is valid for up to three years. For further information, see the *Immunisation Handbook 2011* and the IMAC website: www.immune.org.nz.

CCA is based on the following five assessment areas:

- 1. practice policies
- 2. vaccine reference information
- vaccine stock management
- 4. temperature monitoring and performance
- 5. refrigerator details.

An immunisation provider must meet all the essential requirements for cold chain management to achieve CCA.

If a provider fails to meet the essential requirements the CCA reviewer will work with the provider to develop an action plan including time frames to meet the requirements. If the provider cannot meet the time frames their primary health organisation, medical officer of health and the district health board will become involved.

Provider cold chain policy

Each immunisation provider must have a written current cold chain management policy that specifies actions to be taken in the event of a power/equipment failure. The policy should allocate overall responsibility for cold chain management to a designated person(s). However, each vaccinator is responsible for ensuring that the vaccines they administer have been correctly stored. The cold chain management policy should be dated and signed by relevant staff and reviewed on an annual basis.

Stock management

Immunisation providers should know how much vaccine stock they require at any one time, according to the size of their practice population. They should keep a minimum vaccine stock of two weeks supply but no more than six weeks. Overstocking can lead to wastage in the event of cold chain failure or expiry dates running out.

Dose requirements

The calculation tables below have been developed to help immunisation providers estimate the volumes of National Immunisation Schedule vaccines (excluding influenza) required for their population. The calculations are based on the number of children enrolled at the practice aged under-5 years, and 11 and 12 years (depending on whether a school-based programme is delivered in the region), and assuming 100 percent coverage for all scheduled vaccines. They are also based on the number of times each child is scheduled to receive the vaccine: once for Hib, DTaP-IPV and Tdap; twice for MMR; three times for DTaP-IPV-HepB/HIB, three times for HPV and four times for PCV10.

Practices are entitled to two free deliveries each month from ProPharma.

Vaccine order forms are available on the ProPharma 'National Immunisation Schedule Funded Vaccines' website: www.fundedvaccines.co.nz/vaccines. The online order process is less susceptible to errors, has an audit trail and is faster.

Note that many vaccines are dispatched in boxes of 10. Therefore it is expected that at times immunisation providers' stock levels will be above the maximum level.

Table 1: Two weeks' vaccine supply (number of doses), per population served by practice

<5-year-old population	50	100	250	500	1000	1250
DTaP-IPV-Hib/HepB	2	2	6	12	24	30
PCV10	2	2	8	16	32	40
DTaP-IPV	1	1	2	4	8	10
Hib	1	1	2	4	8	10
MMR	1	1	4	8	16	20
11-and-12- year-old population	50	100	250	500	1000	1250
Tdap*	1	1	2	4	8	10
HPV*	3	3	6	12	24	30

Key: D=diphtheria, T=tetanus, aP=acellular pertussis, IPV=inactivated polio vaccine, Hib=Haemophilus influenzae type b, HepB= hepatitis B, PCV10=10-valent pneumococcal conjugate vaccine, MMR=measles, mumps and rubella, d= adult type diphtheria, ap=adult type pertussis, HPV=human papillomavirus vaccine.

* Tdap and HPV numbers will depend on the number of children vaccinated in a school based programme by public health nurses. School-based programmes should order Tdap in boxes of 10 rather than single doses.

Table 2: Six weeks' vaccine supply (number of doses), per population served by practice

<5-year-old population	50	100	250	500	1000	1250
DTaP-IPV-Hib/HepB	4	8	18	32	70	87
PCV10	5	10	24	47	93	116
DTaP-IPV	2	3	6	12	24	29
Hib	2	3	6	12	24	29
MMR	3	5	12	24	47	58
11-and-12- year-old population	50	100	250	500	1000	1250
Tdap*	2	3	6	12	24	29
HPV*	6	9	18	36	72	87

Key: D=diphtheria, T=tetanus, aP=acellular pertussis, IPV=inactivated polio vaccine, Hib=*Haemophilus influenzae* type b, HepB= hepatitis B, PCV10=10-valent pneumococcal conjugate vaccine, MMR=measles, mumps and rubella, d= adult type diphtheria, ap=adult type pertussis, HPV=human papillomavirus vaccine.

The level of Td (adult type tetanus-diphtheria vaccine) stock required will depend on your practice population, how many people are aged 45 and 65 years are enrolled at the practice and the number of patients the practice sees for acute wound management.

Influenza vaccine orders will be dispatched from Healthcare Logistics as soon as the vaccine is available from the manufacturers (usually in late February or early March). The minimum order for influenza vaccine is 50 doses at the beginning of the season, reducing to 30 and 10 doses nearer the end of the season. The number of influenza vaccine doses a practice orders will depend on the practice population (taking into account the number of chronically ill patients, those aged over 65 years, and those who purchase privately), whether or not it provides an occupational health vaccination service and the size of its refrigerator. Refrigerators should not be overstocked with influenza vaccine.

Influenza vaccine order form details can be found in the National Influenza Specialist Group (NISG)'s annual *Everything you need to know about influenza* kit. For more information see www.influenza.org.nz.

Local immunisation coordinators can assist with working out minimum/maximum stock levels.

^{*} Tdap and HPV numbers will depend on the number of children vaccinated in a school-based programme by public health nurses. School-based programmes should order Tdap in boxes of 10 rather than single doses.

Vaccine receipt and storage by local immunisation providers

When a vaccine delivery arrives at an immunisation provider's premises a designated staff member should immediately check:

- that the vaccines delivered are those that were ordered
- that the vaccines have arrived within the designated time frame (check packing label for time dispatched)
- that all vaccines are within at least one month from their expiry date
- that there is no evidence of exposure to freezing or high temperatures (for example the vaccines are not warm to touch)
- whether any vaccines have NCCA digital monitors and cards attached if they do the NCCA card should be completed and stored with vaccine.

The staff member should then record details of the vaccines (including date received, batch number and expiry date) in a vaccine register/log.

If the vaccine temperature has been outside the +2°C to +8°C range immunisation providers should contact their local immunisation coordinator for advice (*Immunisation Handbook 2011*).

If a provider has concerns about the condition of the delivered vaccines they should notify the ProPharma regional store (or Healthcare Logistics in the case of influenza or privately funded vaccines) and if necessary return the vaccines. Information regarding which vaccines have been returned to the distributor (including batch numbers and expiry dates) should be recorded in the provider's vaccine register.

Vaccines must be left in their packets or packaging: this helps insulate them against thermal insult and protects vaccines sensitive to light. Vaccines must not be:

- stacked against the walls of the refrigerator
- stacked to the top of each shelf
- placed against the rear freeze plate or by the icebox of the refrigerator
- placed in the floor of the refrigerator
- stored in solid trays or boxes (excluding their box packaging).

All vaccines should be stored in an orderly manner, with the expiry date within easy view so that those with the shortest expiry date are used first.

Immunisation providers who are unsure of how to read the NCCA digital monitor should contact their local immunisation coordinator for advice.

Vaccine refrigerator

All immunisation providers must use a pharmaceutical refrigerator for vaccine storage.

The Medicines Act 1981 section 47 'Storage and delivery of medicines', requires that providers must not store vaccines in a cupboard, box or shelf, or to store food in the 'for vaccines only' refrigerator. Vaccines should not be prepared in any room or on any table or bench that is used for packing, preparing or consuming any food or drink (see Appendix 4).

The refrigerator must be:

- in a reasonably sized well-ventilated room, and not in direct sunlight or against a heat source
- against an internal rather than an external wall, to limit exposure to wide temperature variations
- at least 10 cm away from surrounding surfaces, to allow air to circulate around the condenser
- levelled in a way that allows the door to close automatically if left ajar.

The amount of vaccine able to be stored as per the manufacturers' recommendation may be increased, providing vaccines are not stacked against the walls of the refrigerator or to the top of each shelf, and that there is sufficient air circulating.

The refrigerator door seals must be in good condition, to allow the door to close easily and securely. The shelves, and any boxes used, must be of grille type to allow air to circulate. (Solid shelves inhibit air circulation and increase temperature gradients.)

The refrigerator must be left on at all times and have an independent power point and a plug-in surge protection unit. The plug should be taped over, with a written warning against unplugging the refrigerator.

During a power failure, the refrigerator door should be left closed. If vaccines are needed during a power failure, the amount likely to be required for the day should be removed and stored in an insulated container (see Appendix 2). If the power failure extends beyond four hours, providers must seek alternative refrigeration, which can include the use of insulated containers with icepacks (see Appendix 2). Ideally, vaccines should be moved out of a refrigerator without power when the temperature exceeds 8°C.

A refrigeration engineer should check refrigerator function annually.

An insulated container and an appropriate number of ice packs for transport or backup storage must be available.

The Ministry of Health does not recommend the use of domestic (non-pharmaceutical) refrigerators for vaccine storage (Immunisation Handbook

2011). Domestic refrigerators are not designed to maintain the +2°C to +8°C temperature range and they warm up quickly when electricity fails (WHO 1996a). For information on storing vaccines in domestic refrigerators see Appendix 5.

Vaccine refrigerator temperature monitoring

At least two people should be responsible for vaccine storage and temperature monitoring, so that there is someone who can fill in for a designated person during periods of absence.

The provider refrigerator must have an electronic temperature recording device (for example a data logger or temperature logger) that measures the current temperature and the minimum and maximum temperatures reached since the device was last reset. The device should be able to record and download data from the previous month.

The probe of external temperature recording devices should be placed inside the vaccine packaging.

Designated staff must record minimum and maximum refrigerator temperatures on a temperature recording chart, (such as that provided in the *Annual Cold Chain Management Guide*) at least once each working day, preferably at the same time each day and then review these recordings every four weeks. If the temperature falls outside the $+2^{\circ}$ C to $+8^{\circ}$ C range the provider must take appropriate action and document that action on the temperature recording chart. Such action will include contacting their local immunisation coordinator for advice (see also the *Immunisation Handbook 2011's* recommendations in regards to vaccines exposed to temperatures outside $+2^{\circ}$ C to $+8^{\circ}$ C).

Providers must store daily temperature recordings by the refrigerator, to enable all vaccinators to check them before using the vaccines. Temperature records must be archived for 10 years, as per the Health (Retention of Health Information) Regulations 1996.

Providers should be aware of temperature gradients in their vaccine refrigerator. Temperature mapping of the refrigerator, to identify the coldest and warmest parts, can be done using three or more temperature monitors. (Providers can contact their local immunisation coordinator for assistance with this process.)

Only the person designated responsible for the refrigerator should change the thermostat setting; they should do so judiciously, and record the change along with temperature recordings. A specialist may need to adjust the thermostat: providers should first seek the refrigerator manufacturer's advice.

Providers should use an electronic temperature recording device to independently check the refrigerator's performance and thermometer, not less than once every 12 months. Electronic temperature recording devices should be independently calibrated on an annual basis – providers are responsible for ensuring this has occurred (see Appendix 3).

Providers should contact their local immunisation coordinator for assistance in reading temperature recording devices or obtaining temperature recording charts.

Vaccine disposal

Providers should contact their local immunisation coordinator before disposing of vaccines.

Unwanted, discontinued or expired vaccines, and those that have been subjected to thermal insult, should be returned to the ProPharma regional store. They should be **clearly labelled**, with the ProPharma 'Vaccines for Destruction' sticker attached (this is available to download from the ProPharma website: www.fundedvaccines.co.nz/vaccines).

In the case of unusable seasonal influenza vaccines providers should contact Healthcare Logistics to make arrangements for returns and end of season credit for up to 10 doses of influenza vaccine.

If there is a faulty product or there has a cold chain failure involving seasonal influenza or private vaccines supplied by Healthcare Logistics, providers should contact Healthcare Logistics before disposing of them.

Vaccines for destruction should be clearly marked and packed using the standard health and safety precautions that apply to medical sharps waste (for example, using an approved sharps container, or the insulated container the vaccines were delivered, and removing all needles other than those attached to unused prefilled syringes). Providers should list the reason for destruction of vaccines (for example, exceeded expiry date or thermal damage).

Further information on managing events resulting in vaccines requiring destruction can be found in IMAC's 'What to do when things go wrong' guide, available at www.immune.org.nz.

Transporting or storing vaccines in insulated containers

Immunisation providers must use insulated containers (designated transport containers or polystyrene containers) to store vaccines when:

- transporting vaccines
- defrosting refrigerators
- there is a power or equipment failure.

The vaccine temperature must be maintained in an insulated container between +2°C to +8°C at all times.

Only proven methods should be used to transport or store vaccines: for example, insulated containers proven through electronic temperature logging as reliable in maintaining the recommended temperature (solid wall transport containers, double walled transport containers and polystyrene containers), or the cardboard box method used by the ProPharma regional stores.

For more information on transporting and storing vaccines in insulated containers see Appendix 2.

References

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Ministry of Health. 2011. Immunisation Handbook 2011. Wellington: Ministry of Health.

World Health Organization. 1996a. *Guidelines for Establishing or Improving National, Regional and District Vaccine Stores*. Geneva: World Health Organization.

World Health Organization. 1996b. *Managing Cold Chain Equipment: A guide for national logistics officers*. Geneva: World Health Organization.

Appendix 1: National Cold Chain Audit digital monitors and record cards – frequently asked questions

Why was the National Cold Chain Audit suspended in 2011?

In early 2011 a defect was found in a batch of the ColdMark indicators used to monitor temperatures below freezing. This was the second significant quality issue in less than three months. The Ministry of Health and ESR suspended the National Cold Chain Audit (NCCA) between May and October 2011 while the issue was being investigated.

What was changed?

ESR investigated new technologies for temperature monitoring and the decision was made to replace both the heat and freeze indicators with a single digital monitor (TagAlert). The record card was updated with information on the new digital monitor (which is attached to the card).

What did this change mean for providers?

The NCCA process remains the same. Yellow stickers are placed on National Immunisation Schedule vaccine boxes when a digital monitor and record card is attached. The monitors and cards must stay with the vaccine boxes they arrive with. The monitor must be checked and the reading documented when the vaccine is received and whenever a vaccine dose is administered. The monitor should be checked again when the last dose of vaccine in the box is administered and the monitor returned with the record card to the National Vaccine Store. The digital monitor will display an 'OK' symbol if the temperature the vaccines are stored in is between $+2^{\circ}C$ to $+8^{\circ}C$.

What does the digital monitor do if there has been a cold chain failure?

The digital monitor will display an 'OK' symbol if the temperature the vaccines are stored in is between +2 °C to +8 °C. The digital monitor has four 'alerts', one for freezing and three for heat. If any of the alerts are triggered a number from 1 to 4 will display and the 'OK' symbol will have a black box around it. The digital monitor does not make any alarm sound and so should be checked regularly.

What do I do with the vaccines in my vaccine refrigerator if the monitor displays alerts?

If at any stage the monitor displays any of the alerts from 1 to 4, none of the vaccines in the provider's refrigerator should be used as it is likely all the vaccines have experienced a cold chain failure not just the vaccine box with the monitor attached. Label the vaccines 'Not for Use' and contact your local immunisation coordinator to discuss further action.

What do I do if the digital monitor displays alerts when I receive my ProPharma order?

If the digital monitor displays any of the alerts from 1 to 4 when your vaccine orders arrive from the ProPharma regional store, place the vaccines in your refrigerator and label 'Not for Use'. Contact your local immunisation coordinator to discuss further action.

What does it mean if the monitor display is blank when I receive my ProPharma order?

A blank display on the unit means that it has not been turned on or the battery is flat, this can be checked by pressing the start button. If the monitor activates, an 'OK' will display. Immediately place the digital monitor and the vaccines it arrived with in the fridge and document when the monitor was started on the record card. If the digital monitor does not start contact the National Vaccine Store.

Why does the record card have both warm and cold columns when digital monitor only displays OK?

The record card has both columns as the digital monitor displays both warm and cold alerts.

How long will the battery last on the monitor?

The digital monitor checks the temperature every five minutes, which allows the monitor to last at least 12 months from the time it is switched on.

What do I do if the digital monitor battery runs out and there are still vaccines left in the box?

Contact the National Vaccine Store who will arrange for another digital monitor and record card to be sent to you.

How many digital monitors and record cards are issued?

When vaccines are dispatched from the National Vaccine Store only a small proportion of National Immunisation Schedule vaccines will have monitors and record cards attached. Providers are not sent a digital monitor and record card with every vaccine delivery.

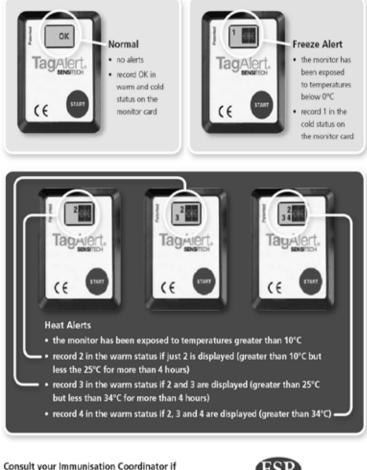
Which vaccines will be issued with a digital monitor and record card?

Only National Immunisation Schedule vaccines will be issued with a NCCA digital monitor and record card. These vaccines are Infanrix-hexa, Synflorix, Act-HIB, MMR, Infanrix-IPV, Boostrix, Gardasil and the ADT Booster.



National Cold-chain Audit

Cold-chain Monitor Quick Reference guide



Consult your Immunisation Coordinator if the monitors display alarms 1,2,3 or 4.

DO NOT remove vaccines from the fridge or dispose of vaccines without advice from your Immunisation Coordinator.



Appendix 2: Transporting and storing vaccines in insulated containers

The following factors need to be considered when transporting or storing vaccines in insulated containers:

- 1. The amount of vaccine to be transported or stored will determine the size of the insulated container required, but the volume of vaccine to be transported or stored should not exceed one-third of the container's capacity.
- 2. Ice packs must be frozen, not refrigerated. When freezing the required ice packs, providers should set them on their edge in the freezer and space them to allow for even freezing.
- 3. The number of icepacks needed to keep the vaccines at +2°C to +8°C for the duration of transportation or storage will in turn depend on the size of the container. Icepacks should be the flat bottle type, about 35mm thick or the large gel pack variety (eg, Enviro freeze), as slimmer models tend to thaw out more quickly.
- 4. There should be enough ice packs to cover one layer of the insulated container.
- 5. Icepacks should be frost-free before they are placed in the insulated container (ice should no longer form on their surface).
- 6. There is a risk of vaccines freezing if icepacks are not used correctly. Note that fewer commercial icepacks may be required to achieve the recommended temperature range of +2°C to +8°C, and that additives to some commercial icepacks depress their melting point.
- 7. A maximum/minimum digital thermometer or data logger must be used to monitor the vaccines throughout the duration of transportation or storage.
- 8. The length of time the vaccines will be transported or stored should be taken into consideration.
- 9. The external environment the insulated container will be exposed to should also be taken into consideration (eg, seasonal extreme temperatures in some regions).
- 10. For transportation of vaccines over longer periods of time (for example, school-based immunisation programmes or an outreach immunisation service), providers should carry an extra transport container of frozen slicker pads or Enviro freeze to top up the vaccine-carrying transport container as necessary to maintain the temperature at +2°C to +8°C.

Packing vaccines for transport or storage

- 1. Put approved insulation material (eg, shredded paper or a sheet of 10 mm thick polystyrene foam) in the bottom of the insulated container (to take up one-third of the container's capacity).
- 2. Place a layer of shredded paper or a sheet of 10 mm thick polystyrene foam sheet on top of the vaccines, to ensure the vaccine will not be frozen by contact or exposure to the icepacks. A polystyrene foam sheet should sit flat on top of the vaccine and not stick on the sides, then place the vaccine in such a way that the most heat sensitive are nearest the icepacks and the most freeze sensitive are furthest away.
- 3. Place the required number of icepacks on top of the shredded paper or polystyrene foam sheet. Icepacks should be frost-free before they are placed in the insulated container; that is, ice should no longer form on their surface. This means that the temperature of the icepack is at least o°C, reducing the risk of freezing vaccines.
- 4. Place the probe of the data logger or minimum/maximum thermometer in a box of vaccine: ideally in the middle of the transport container and closest to the ice packs. This is because there is a greater risk to the vaccine from freezing than from the temperature going above +8°C.
- 5. Fill the remainder of the insulated container with shredded paper.
- 6. Secure the lid using the clips on the container; if necessary tape it in place.

This method has been demonstrated to keep the temperature within +2°C to +8°C for up to five hours, even if the insulated container is opened briefly up to four times in a warm room during that time.

Opening the container more frequently, or opening it for periods longer than one minute or transporting vaccines in a hot motor vehicle are likely to reduce the time the temperature can be maintained within the recommended range.

Diluents can be transported or stored at room temperature (although note that the Infanrix-hexa vaccine Hib pellet and Act-HIB vaccine diluent should be kept with the vaccine components in the box they arrive in).

Appendix 3: Electronic data loggers and digital minimum/maximum thermometers

Electronic data loggers

Data loggers are recommended as the gold standard for immunisation providers to monitor the cold chain of the vaccines they store or transport. In the event of a power failure or other cold chain breach, they provide a means of identifying how long the vaccines have been exposed to adverse temperatures. Immunisation coordinators use data loggers to assist providers in managing their cold chain. Outreach immunisation services and school-based programmes also often use data loggers to monitor the temperature of the vaccines that they are transporting.

An increasing number of brands of electronic data loggers are available for use. They have the following characteristics in common (note that providers should always be aware of the individual manufacturers' specifications).

- The manufacturer's guarantee ranges from one through to three years.
- The loggers' accuracy at 0° C ranges from \pm 0.2 to 0.3°C between -10 to $+70^{\circ}$ C.
- Manufacturers' consider their lifespan to be up to and exceeding five years, depending on the environment in which they are being used (for example, the temperature range they are exposed to, the sample rate/logging interval, and the number of uses) and whether they are being used correctly.
- Manufacturers recommend annual calibration by an independent International Accreditation New Zealand (IANZ) accredited laboratory.

In addition some manufacturers recommend that data loggers be ice pointed (see below) six-monthly.

Purchasers of electronic data loggers should:

- request a manufacturer's certificate of accuracy –either in-house certificate or through IANZ
- ice point the data logger following purchase and before use, in order to know where within the specified accuracy range that particular logger falls, given the accuracy of data loggers' ranges from \pm 0.2 to 0.3°C and the fact that the full spectrum of this range is likely to be found within a single manufacturing run

• thereafter ensure data from the logger is downloaded on a regular basis (for example, once a month or whenever there are daily temperature recording outside the +2°C to +8°C range). The data from the logger maybe stored electronically (provided it is backed up) or on a paper system with your daily minimum/maximum recordings. The use of the data logger does not replace the requirement for daily recordings.

It is the practice of some immunisation coordinators to routinely use three data loggers to concurrently monitor different areas within a refrigerator; this method has found temperature gradients similar to those Grassby (1993) found: for example, -1.30 to $+7.43^{\circ}\text{C}$, -3.30 to $+7.33^{\circ}\text{C}$, +2.96 to $+9.40^{\circ}\text{C}$.

Grassby recommends using calibrated thermocouples (equivalent to electronic data loggers in the New Zealand situation) at three locations within a refrigerator cabinet, to confirm the mean temperature profile together with cyclical temperature fluctuations.

In light of these findings, and the fact that providers do not limit the storage of vaccines to the only area of the refrigerator being monitored, those responsible for undertaking regular assessment of vaccine refrigerators should routinely monitor at least three sections or areas of the refrigerator annually.

Digital minimum/maximum thermometers

Providers should have a digital minimum/maximum thermometer available for use during a power outage and when transporting vaccines. Such thermometers are a low-cost means of monitoring refrigerator ambient air temperatures.

A number of digital minimum/maximum thermometers are available; most have the following characteristics in common:

- The manufacturer's guarantee applies for one year only.
- Their accuracy at 0° C ranges from ± 0.5 to 1.0° C.
- The battery requires replacing yearly (one model) to two-yearly (three models).
- Their lifespan is in the vicinity of three years if used correctly after this time their accuracy range is likely to decrease, due to the electronic circuitry and battery degrading.

Given that the accuracy of such thermometers ranges from \pm 0.5 to 1.0°C and that the full spectrum of this range is likely to be found within a single manufacturing run, providers should ice point the thermometer following purchase and before use, in order to know where within the accuracy range that particular thermometer falls.

Performing an ice point test

Perform an ice point test as follows:

- Take about a cup of ice and remove any white frosty parts by rinsing in water.
- Crush the ice cubes to pea size.
- · Place in a cup without water.
- Take the probe and place it in the ice.
- Leave for approximately five minutes, or until the reading stabilises.
- The thermometer should read $o^{\circ}C$ (ice point) \pm the manufacturer's stated accuracy specification.

The difference between accuracy and resolution

Digital minimum-maximum thermometer and data logger specification sheets include accuracy (sensor measurement) and resolution (display) specifications. These are two different things and should not be confused.

- 1. Accuracy is the degree of refinement in measurement: that is, what the electronics would theoretically be capable of achieving if the resolution was infinitely small. Thermometer accuracy ranges from 0.5°C to 1.0°C, and data logger accuracy ranges from 0.2 °C to 0.3°C.
- 2. Resolution is the smallest interval measurable by the thermometer or data logger i.e. the steps indicated by the temperature table. Thermometer resolution ranges from 0.02°C to 1.0°C and data logger resolution ranges from 0.02 °C to 0.4°C.

For example, if a thermometer or data logger displays 0.02°C and increment it does not mean it is accurate to 0.02°C.

For this reason manufacturers recommend that where loggers are used in a specific situation (application), the average temperature of that application should be in the middle of the logger's range, where resolution and with it the capability of displaying an accurate value will be best.

Appendix 4: Medicines Act 1981 section 47

Storage and delivery of medicines

- No person who is in possession or charge of any prescription medicine or restricted medicine shall put it:
 - a) in any cupboard, box, shelf, or other place of storage in which articles of food or drink are stored or kept for ready use; or
 - b) in any place to which young children or unauthorised persons have ready access.
- 2. No person shall pack any medicine, or prepare it for use, in any room, or on any table or bench, that is used for the purpose of packing, preparing or consuming any food or drink.
- 3. Except as otherwise provided in any regulations made under this Act, no person who is in possession, for the purposes of any business, of a prescription medicine or a restricted medicine that is kept for the time being within any building or vehicle, shall leave that building or vehicle unattended unless he has taken all reasonable steps to secure that building or vehicle, or the part of it in which the medicine is kept, against unlawful entry.
- 4. No person shall deliver on retail sale, or in circumstances corresponding to retail sale, any medicine otherwise than through the post or by handing it or causing it to be handed to the person, or another person reasonably believed to be acting on that person's behalf, to whom it is addressed or for whose use it is intended.
- 5. Every person commits an offence against this Act who, without reasonable excuse, contravenes any of the provisions of this section.

Appendix 5: Vaccine storage in domestic (non-pharmaceutical) refrigerators

All immunisation providers must use a pharmaceutical refrigerator for vaccine storage.

The Ministry of Health does not recommend the use of domestic (non-pharmaceutical) refrigerators for vaccine storage (*Immunisation Handbook 2011*). Domestic refrigerators are not designed to maintain the +2°C to +8°C temperature range and they warm up quickly when electricity fails (WHO 1996a).

The refrigerator must have an electronic temperature recording device (for example a data logger) that measures the current temperature and the minimum and maximum temperatures reached since the device was last reset.

Vaccines should be stored according to temperature sensitivity and the temperature mapping of the refrigerator. Live vaccines (for example, BCG, MMR, and varicella) should be kept in the coolest part of the refrigerator, and freeze sensitive vaccines in the warmest part.

In a domestic type refrigerator, total storage used must not exceed 50 percent of the refrigerator's storage capacity (and only the monitored section of the refrigerator should be used due to the variable temperature zones within a domestic type refrigerator cabinet and because the temperature gradient increases in proportion to the degree of packing (Grassby 1993)).

The average general practice immunisation provider will require a refrigerator of approximately 180 – 200 litre capacity to meet the Grassby (1993) and WHO (1996) recommendations. Practices with multiple general practitioners may require larger refrigerators. An under-bench domestic type refrigerator is approximately 140 litres and therefore is of insufficient size for the average general practice immunisation provider. This type of refrigerator is only suitable for a sole practitioner.

Freezer shelves should be filled with ice packs or plastic bottles of plain water.

Vaccine should not be stored in the doors of domestic refrigerators.

Non-self-defrosting refrigerators should be defrosted before 5 mm of ice forms on the icebox (if present). Ice forming unevenly over the icebox or back plate may indicate impaired refrigerator function and a refrigeration engineer should check the

refrigerator. Non self-defrosting refrigerators should have a drip tray under the icebox. Self-defrosting refrigerators should have clear flowing drip tracks.

During defrosting, vaccines should be removed to a second monitored refrigerator, or stored in an insulated container.

Water buffers (bottles filled with salt water) should be placed in empty spaces (for example on the floor and in the door) to assist in preventing temperature swings when the door is opened.

Appendix 6: Key contacts

Regional immunisation advisors (IMAC)

Northern: Phone: 027 497 6971

Email: imacnth@ihug.co.nz

Central: Phone: 027 232 4567

Email: imaccent@ihug.co.nz

South Island: Phone: 027 242 2451

Email: imacsth@ihug.co.nz

For immunisation coordinator contact details, contact the regional immunisation advisor for your region or the Immunisation Advisory Centre.

Immunisation Advisory Centre (IMAC)

PO Box 17 360 Greenlane Auckland 1546

Phone: (0800) IMMUNE (0800 466863) or (09) 373 7599

Institute of Environmental Science and Research (ESR) – National Vaccine Store

34 Kenepuru Drive PO Box 50-348 Porirua 5240

Phone: 0800 4ESR EH (0800 437 734) Option 2 or (04) 914 0792

ProPharma regional stores

ProPharma provides a vaccine distribution service only, not a technical inquiry/ assistance service. All technical inquiries should be directed to the local immunisation coordinator or regional immunisation advisor in the first instance.

ProPharma vaccine order forms and vaccine orders can be placed online at: www.fundedvaccines.co.nz/vaccines.

National Immunisation Schedule vaccine order forms can also be obtained from ProPharma regional stores and faxed to the following numbers:

ProPharma Whangarei	(09) 438 9681
ProPharma Auckland	(09) 570 1081
ProPharma Hamilton	(07) 957 3850
ProPharma Wellington	(04) 576 1811
ProPharma Christchurch	(03) 389 5459
ProPharma Dunedin	(03) 474 5061

Healthcare Logistics

The Healthcare Logistics customer service number is (09) 969 0736.

Seasonal influenza vaccine ordering is currently handled by Healthcare Logistics on behalf of the manufacturers. Influenza vaccine can be ordered online at: www.hconline.co.nz

Alternatively, there is a NISG seasonal influenza vaccine order form in the annual 'Everything you need to about influenza' kit and is available to download from www.influenza.org.nz

Seasonal influenza vaccines can be ordered from Healthcare Logistics by fax to 0508 408 358.

Vaccine manufacturers

The vaccine manufacturing companies also provide technical assistance with regard to cold chain problems.

The companies supplying vaccines for the National Immunisation Schedule are:

- GlaxoSmithKline (GSK) (phone o800 822 2463)
- Merck, Sharp & Dohme (NZ) Ltd (MSD) (phone o800 500 673)
- Sanofi-Aventis (NZ) Ltd (phone og 580 1810)
- CSL Biotherapies (New Zealand) (phone o800 502 757)
- Pfizer (New Zealand) (phone o800 736 363)