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சுகாதார பராமரிப்பு மற்றும் போஷணை அமைச்சு  
Ministry of Healthcare & Nutrition

All Provincial Directors of Health Services,  
Regional Directors of Health Services ,  
Director, N.I.H.S., Kalutara,

**Guidelines for handling and storage of vaccines in the private sector**


It has been well accepted that there is a well established cold chain maintenance system operates in the state sector with the active involvement of the Epidemiological Unit, Family Health Bureau and other relevant agencies of the Ministry of Health. However, such a system is not in place in the private sector.

A meeting was held to discuss about this issue and to develop guidelines for handling and storage of vaccines in the private sector with the participation of all the stake holders on 04<sup>th</sup> June 2009. The attached document named as “**Interim guidelines for handling and storage of vaccines in the private sector**” was the final outcome of the meeting.

Ministry of Health expects that;

1. these guidelines are distributed to all the private sector health establishments including pharmacies, wholesalers, dispensaries, nursing homes and hospitals.
2. compliance of the guidelines by the above parties is periodically monitored by you and other Authorized Officers and, reported to Director, Medical Technology and Supplies (D/MT&S) and the Epidemiological Unit.

You are hereby advised to make the above duties as important and essential that should be carried out by the Authorized Officers functioning under your administration.

  
Dr. U.A. Mendis,  
Director General of Health Services

Copy: Secretary Health

## Guidelines for Handling and Storage of Vaccines in the Private Sector

### Introduction:

The “cold chain” is the name given to a system of people and equipment which ensures that the correct quantity of potent vaccine reaches the recipients who need it from the point of production. The cold chain system is necessary because vaccines are delicate substances that lose potency if they are exposed to temperatures that are **too warm or too cold**. Administration of vaccines is useless if the vaccine that was used is not potent!

Vaccine must stay at the **correct temperature** throughout the entire cold chain system – when it is **transported**, when it is **stored** in a refrigerator or cold store, and when it is **used** at the time of administration.

The two essential elements of cold chain system are:

- Trained persons to manage vaccine storage and distribution
- Correct equipment to store and transport vaccines and monitor temperature

People are an extremely important part of the cold chain. **Even if the finest and modern equipment is available, the cold chain will not be effective if people do not handle vaccine and equipment properly.**

The basic cold chain equipment includes:

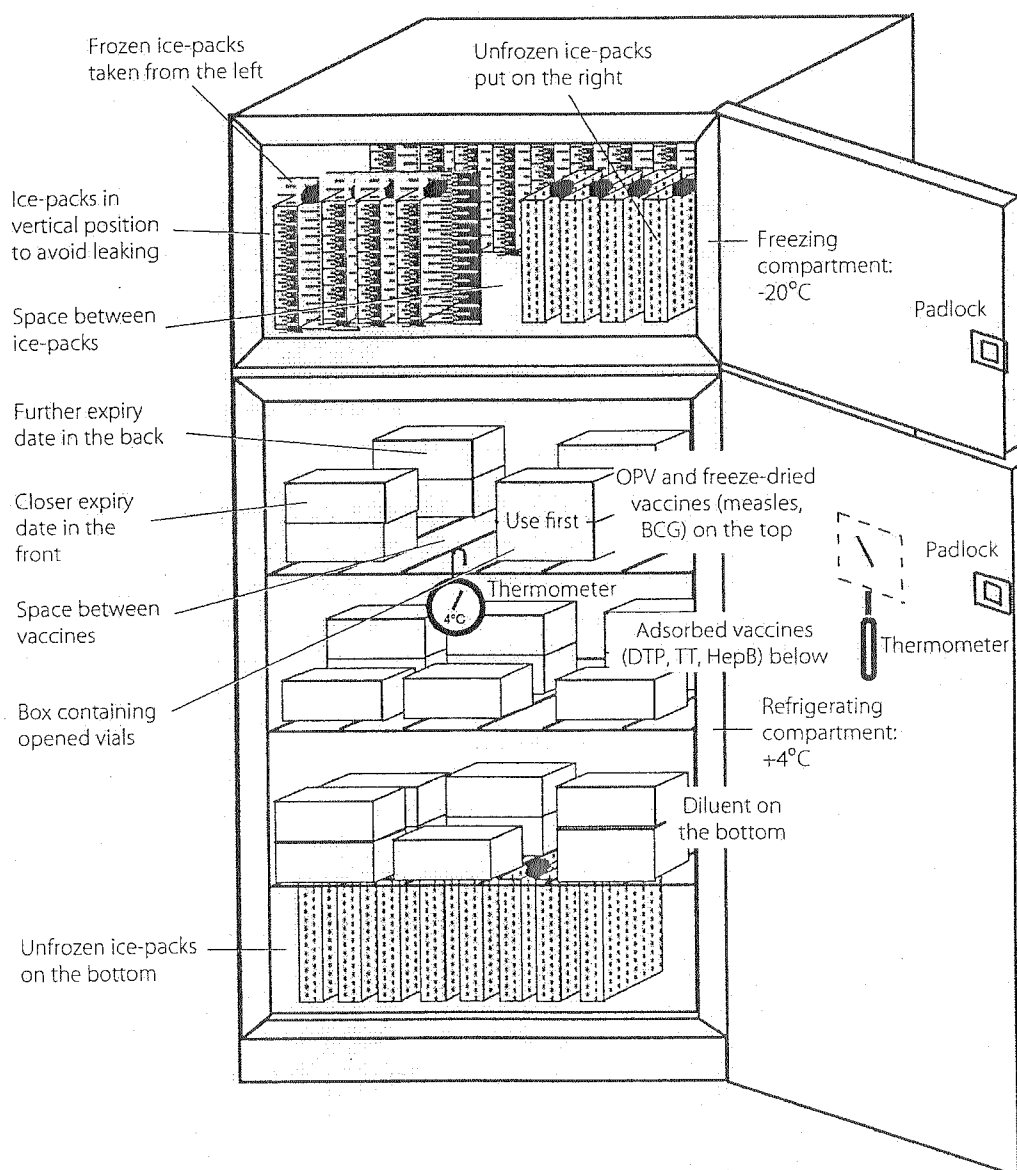
- For vaccine storage : Refrigerators and Cold-rooms.
- For vaccine transport: Cold boxes, Vaccine carriers, Day-carriers and Thermos flasks.
- For cold chain monitoring: Thermometers, Cold Chain Monitors, Vaccine Vial Monitors, Freeze Watch Monitors and data loggers
- For transport : Vehicles

### RECEIPT OF VACCINES

1. On receiving a consignment of vaccines, one designated staff member should check the vaccines for leakage, damage, labeling and discrepancies against the order and ensure that the vaccine containers have arrived in good condition
2. At no time should vaccines be allowed to be frozen, exposed to higher temperatures, direct sunlight or fluorescent light.
3. Vaccines should ideally be checked, as stated above, in an A/C room.

4. Vaccines must be refrigerated immediately on receipt and not be left at room temperature
5. After checking, the entire consignment must be stored at  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$  in the cold storage facility and/or vaccine refrigerator/s
6. Vaccine type, brand, quantity, batch numbers and expiry dates should be recorded, with the date and time at which they were received, to facilitate first-in/first-out monitoring
7. In retail outlet / hospital/ dispensary vaccines should not be stored more than average two months requirement.

## STORAGE





13. No other item(eg. Other drugs, food, drink) should be stored in vaccine refrigerators
14. Temperature of the refrigerators/cold storage facility must be monitored twice a day, by a designated member of staff, using thermometer and records of same must be maintained in the temperature monitoring sheets as given in the annexure.
15. Thermometer should be regularly checked to ensure that they are working properly
16. The arrangement of the stocks should be such that those with a shorter expiry date are easily accessible for use before those with longer expiry dates. This will ensure that the newly received vaccine will be used after those received earlier.
17. Generator should be available, that get switched on automatically (i.e. equipped with an auto-on switch) in the event of a power failure
18. Refrigerators/cold storage facility must either be lockable or within a room that is locked when not occupied by a member of staff
19. Opening of the refrigerator door should be kept to a minimum
20. Refrigerators/cold storage facility must be checked and serviced regularly, and records or such checks and services be maintained

#### **TEMPERATURE FLUCTUATION/PRODUCT DEVIATIONS**

21. In the event of a temperature fluctuation above +8°C or below +2°C for a period exceeding 6 hrs, the pharmacy/vaccination centre should immediately stop selling the vaccines in question and inform the Importer or Distributor immediately for necessary action
22. Any other product deviations(eg. change of colour/leakages/damaged packs) detected by the staff, has to be brought to the notice of the importer/distributor immediately for necessary action

#### **ISSURING OF VACCINES**

23. Intact/undamaged cool boxes or regifoam boxes with tight fitting lids should be used when vaccines are given to patients to be taken out of the pharmacy.
24. Some vaccines and biological products when come into contact with ice or sub zero temperature may loose its potency. Hence vaccines should not be dispensed in polythene bags in contact with ice.

25. The appropriate number of activated coolants/gel/ice packs must be used to ensure the required temperature of +2°C to +8°C is maintained until the vaccine is administered or until the vaccine is stored back in a refrigerator
26. Coolants/gel packs must be removed from the freezer, 30 minutes prior to being packed, to allow them to 'sweat'. This reduces the risk of freezing vaccines
27. Vaccines should not come into direct contact with ice packs. The use of regiform packing material or other equivalent (eg. shredded paper, cardboard, bubble wrap) is recommended
28. Vaccines should be dispensed only on prescription by a pharmacist and the consumer needs to be briefed/advised on the importance maintaining the cold chain in transit and proper storage
29. Records of the prescription to be maintained in the prescription register. In addition, a register should be maintained at every retailer or dispensing outlet providing number of doses of each type of products received, sold, their batch numbers and expiry dates and should be submitted such data quarterly to the importer/distributor to be submitted to D/MT & S.
30. Vaccines should not be re-sold to other pharmacies and /or outlets