WS 1 – Appendix 14

Points of attention for good vaccine management

This document is prepared to serve GDP training purposes.

The path that vaccines take from manufacturer to storage location and to the end user needs to ensure that a cold chain process is maintained. In this context of COVID-19 vaccines, the responsibility for the vaccines will be managed by the responsible pharmacist who will ensure that upon delivery of the vaccines at each vaccination administration location, cold chain is maintained.

Each of the three Vaccination Administration Locations will have dedicated cool boxes (active cool boxes) which will be managed collaboratively between the pharmacist and the operation logistics manager and the team member dedicated to ensure that vaccine equipment is properly monitored and logged.

Good vaccine management requires the following:

1. Training
   - A person responsible for vaccine management is designated. This person is demonstrably trained in GDP aspects (Good Distribution Practices). This document can be used for this purpose whereby the document is dated and signed off by the responsible person for having read and fully understood.

2. Reception
   - Upon receipt of the vaccines, a recorded receipt check is made, including: date and time of receipt, vaccine name, quantity, batch number, temperature data of transport.
   - If the received vaccine or vaccine package is damaged, it should not be used. Keep the vaccine separate and contact RIVM: 088-678 8900, dial 1.

3. Storage *where vaccine is stored*
   - When placing in the refrigerator:
     - Do not place vaccines against the back of the refrigerator. Also, do not place vaccine on the bottom plate or against the top wall of the refrigerator.
     - Do not load the refrigerator more than 70% to ensure good air flow.
     - Leave the refrigerator open for as short a time as possible so that the temperature remains between 2-8 °C as much as possible
     - Check that there is no excessive icing in the refrigerator, this may indicate an underlying technical defect

- If several batches of the same product are present, the products that expire first (see expiration date) are used first; the so-called first-expired-first-out (FEFO) principle. Place the oldest products at the front of the refrigerator so that the FEFO principle can be implemented easily and without error.
- Make a daily print-out of the temperature logger in the refrigerator (See appendix 1; 'Requirements for the refrigerator'). If it is not possible to print out the temperature logger, the temperature must be read twice daily and recorded in a logbook. The person who does the registration also signs for this. Ensure proper archiving.
- In case of an irregular picture of the temperature development: Read out the logger more often and take timely action to prevent anomalies.
- For temperature deviations, see under 'special situations'.

4. Use of vaccines

   - Use the vaccines according to the instructions in the RIVM guideline.
   - Vaccines may only be used if the batch number is clear and if the expiry date / time has not yet passed. If the vaccine must be transported for administration to a patient on site: see Appendix 2.
   - Do not leave vaccine unattended (e.g. during breaks).
   - Empty vaccine vials should be disposed of in a WIVA container. This container will be disposed as outlined in the waste management section of the operational plan.

5. Repackaging and distribution of vaccines

   In accordance with the *Medicines Act*, the repackaging and distribution of vaccines is only reserved for organizations with a manufacturer's license that states the intended actions for registered medicines. Repackaging must be carried out in accordance with the provisions of the GMP (Good Manufacturing Practices). Distribution must take place in accordance with the provisions of the GDP (Good Distribution Practices).

Given the unique situation with the COVID-19 pandemic, it is possible, under certain conditions, to temporarily and in a controlled manner deviate from these regulations, exclusively for the benefit of the Covid-19 vaccine. To this end, the responsible pharmacist in consultation with Inspectorate of Public Health, Social Development and Labour (VSA) has made arrangements to deviate from existing legislation and procedures with regards to storage.

It is important that the quality and safety of the vaccine remains guaranteed during repackaging and distribution to the various vaccination administration locations, that measures are taken to prevent theft and that the vaccine remains fully traceable in the chain.

- <u>Transport from central storage location to each vaccination administration location</u>
  - The pharmacist will be responsible for distribution of the vaccines to each vaccination administration location. The pharmacist will be escorted by KPSM.

- Each Vaccination Administration Location will have its own cool box. A fourth cool box will be used by the pharmacist to assist with the distribution.
- At midday, the pharmacist will visit each site location to take inventory and ensure that cold chain is maintained by the designated staff member at each location.
- The pharmacist will ensure that cold chain will be maintained with each delivery including hand off the cool boxes (active cooling). If the vaccine is transported to another vaccination site, the cold chain remains secure at all times. Different transport properties may apply for each vaccine. This needs to be taken into account. For example, the Pfizer vaccine may only be transported before it has been diluted with solvent.
- For transporting vaccines at 2-8°C, cool boxes will be used
- Create a file per transport with the printout of the temperature logger. Check the print-out and sign for approval. In case of a temperature deviation, see under 'Special situations'.

Special situations:

a) Cold chain incident
   - In the event of cold chain incidents (temperature outside specification of 2-8°C), RIVM is contacted immediately (telephone number: 088-678 8900, dial 1). The Inspectorate of VSA will also need to be notified. In consultation with the quality manager of RIVM and Inspectorate VSA, a decision is made whether the vaccine may still be used. Until that decision is made, all vaccines involved will be identified as such and placed separately in the refrigerator.

b) Expanded vaccine
   - Vaccines that are past the expiry date should be disposed of immediately. This product will be disposed of per waste disposal procedures outlined in the operational plan.
   - Vaccines that should no longer be used are disposed of in a WIVA container.

c) Product complaint
   - Vaccines in which there is a product complaint (product complaints refer to complaints about the vaccine, such as broken glass, abnormal color of the vaccine or if there are external deviations from the contents) must be reported to the pharmacist who will then contact RIVM, telephone number: 088-678 8900. The Inspectorate VSA will also need to be notified in writing. The vaccine vial must be kept separately from the other vials, giving details of the complaint and the location. The latter is necessary in order to provide feedback later.

Appendix 1 Requirements for (the use of) medicine refrigerators

Two refrigerators were provided by the RIVM to St. Maarten. The refrigerator will conform to the requirements below. The refrigerator will be validated by the pharmacist using RIVM validation protocol.

Refrigerators should meet the following requirements:

- The refrigerator is a medical refrigerator: a regular consumer refrigerator will not do;
    - A medicine refrigerator does not include a freezer compartment, as this creates an imbalance of temperature distribution in the refrigerator.
    - A medicine refrigerator does not have storage compartments in the door, as they are not suitable for putting down medicines.
- Preferably, the refrigerator has been pre-qualified by the supplier for its intended use, there will be a certificate showing which tests have been successfully passed.
    - The temperature distribution (distribution) inside the refrigerator with the door closed can be shown to be maximum +/- 1°C.
    - The temperature logger in the refrigerator is calibrated to max 0.5°C accuracy. Calibration is the process of comparing the measurement to an accepted reference measurement.
    - In the event of a power outage, the refrigerator can maintain the temperature (with the door closed) between 2-8°C for at least one hour when the room temperature is up to 30°C.
- The medicine refrigerator has a minimum temperature range of 2-8°C. The optimum storage temperature is 5°C.
- The temperature setting of the refrigerator can be set at 0.5°C intervals.
- The medicine refrigerator will sound an alarm when power is interrupted. The refrigerator's alarm system is calibrated.
- The medicine refrigerator provides a visual and/or audio alarm when the temperature is outside the set temperature range.
- The calibrated temperature logger logs the temperature progression in the refrigerator.
- The refrigerator itself or the room in which the refrigerator is located must be locked.
- In the event of refrigerator failure, an emergency solution should be in place to move the vaccines.

Appendix 2 Requirements for mobile refrigeration solutions

Purpose: Refrigerated transport of vaccines (2-8°C) from distribution point to storage site (or vice versa) or from storage site to patient in home situation.

Precondition: transport takes place on one day, is as short as possible, and preferably lasts a maximum of 4 hours from start to finish;

Active and passively cooled coolers:
For transporting vaccine where the cooler will be opened several times, actively cooled coolers are preferred. This means: with a cooling motor and a plug to connect the cooler to 220V or 12V. An actively cooled box is better able to keep the temperature within specification when repeatedly opening a box with small contents. Active cool boxes will be used on St. Maarten to transport from central location to the vaccination administration locations.

For direct transports from A to B without a stop where the cooler/bag is opened, a passively cooled cooler/bag is sufficient.

General requirements for coolers/cooling bags (actively and passively cooled)
- Cool box or cooler bag must be for medical purposes, for example, a camping cooler will not suffice for transporting medicines;
- The cooling solution is preferably qualified for the intended use, there is then a certificate present stating for what duration and under what conditions the cooled temperature is guaranteed;
- The cooler has an easy-to-understand user manual regarding the use of the cooler and the reading of the temperature logger.
- Preferably, the cooler has an integrated temperature logger that can be removed from the cooler for reading.
- A temperature logger (integrated or not) meets the following requirements:
    - The temperature logger is calibrated to max 0.5°C accuracy.
    - The temperature logger has a start/end button that records the temperature progression during transport.
    - The temperature logger gives an immediate visual indication when the temperature has been below 2 or above 8°C.
    - The temperature logger can be read out on a computer and the result (graph or table) can be printed out.
- If there is no integrated temperature logger, a separate temperature logger should be added, placed between the vaccines. At that location, a proper temperature measurement can be made. The temperature logger is provided by the distributor in the vaccine package.
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NB In the event of deviation from the temperature during transport, advice must be sought immediately from the quality manager at RIVM. The vaccine may not be used until permission has been granted.

Additional requirements for an **actively** cooled cooler
- The cooler can be pre-cooled at the start location
- The cooler has a valve in the lid that allows vaccine to be taken from the box without having to open the entire lid (prevents cold loss)
- If the cooler needs continuous power, it is important that it has a splitter plug that can be connected to both the mains and the 12V socket in a car.

- For the purpose of the vaccination administration locations on St. Maarten, it is the intention that these cool boxes will stay on location and be returned to the storage location at the end of each day in order to prepare for the the next day.

Additional requirements for a **passively** cooled cooler or cooler bag

- At a minimum, the specifications should state for how many hours the cooled temperature is guaranteed at room temperature. Choose a solution that is guaranteed to remain cool for twice the duration of the intended transport;
- A good cooler always has separate compartments for the medicine and the cooling elements. The cooling elements should never be placed in the same compartment as the vaccines because the vaccines may freeze! (A solution to separate the cooling elements from the vaccines using cardboard, for example, is completely inadequate)
- During transport, cooling elements will condense. To prevent the vaccine package from getting wet, the vaccine should be packed, in the cooler, in a plastic bag.
- The cooler has an easy-to-understand user manual regarding freezing the cooling elements, using the cooler and reading the temperature logger.
- The cooling elements should be kept in the freezer for at least as long as the owner's manual specifies.
- When in use, the cooling elements must be placed in the cooler in accordance with the instructions. Never place less or more elements than the manual indicates.

For the purpose of COVID-19 vaccine, passively cooled bags will note be used.