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**PQS Target Product Profile**

**TITLE: Enhanced refrigerator or combined refrigerator and water-pack freezer: solar direct drive**

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**Contents**

## 1. Need

Recent public sector consultations and reports from the field have identified the need for some amendments and additions to the current PQS specifications for solar direct drive (SDD) equipment. Initial field experiences with first generation SDD products has revealed certain shortcomings in performance and build quality and has also highlighted usability issues relating to installation and maintenance. These matters need to be addressed so that the next generation of SDD equipment better meets country needs.

The purpose of this preliminary Target Product Profile is to propose enhancements designed to resolve these issues and to initiate a consultation process with industry which will lead to revised PQS performance specifications and verification protocols and to products with improved overall performance.

## 2. Normative references

Refer to relevant PQS specifications and verification protocols.

## 3. Terms and definitions

Acceptable temperature range:

- The acceptable temperature range for storing vaccine is +2.0°C to +8.0°C. However, transient excursions outside this range will be tolerated, within the following limits:

  1. No excursion must exceed [+10°C±0.5°C][1].

  2. No excursion must be below [+1.5°C ±0.5°C].

  The cumulative effect of any excursions within the above range will be assessed over the five day period of the day/night test. For this test, the calculated mean kinetic temperature (MKT)[2] must remain within the range +2.0°C to +8.0°C when the default activation energy is set at 83,144 kJ per mol. Using the recorded temperature data, an MKT figure will be calculated for each sensor. The worst-case result will determine the outcome of the test. Excursions in other tests will be noted. None of these excursions must exceed the upper and lower limits defined above.

**Reason for change:** Excursion criteria should be tightened in order to exclude the possibility of freezing vaccines and also to reduce the upper excursion limit to achieve greater compliance with the designated +2.0°C to +8.0°C operating range.

**Timing for PQS Inclusion:** 2015

Freeze-protection classification:

- Grade A, user-independent freeze protection (UIFP): when the appliance is used within its nominated temperature range (temperature zone +43°C, +32°C or +27°C and minimum rated ambient temperature) there is no intervention required

[1] Brackets indicate a proposed change from the current specifications

[2] Refer to Seevers, R. et al. *The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals*. Pharmaceutical Outsourcing, May/June 2009.

by the user to ensure that the vaccines will not be exposed to temperatures below 0°C whatever the position of the vaccine in the vaccine compartment.

- Grade B, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items to avoid vaccine freezing constitute one level of intervention by the user).
- Grade C, user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring several levels of intervention (e.g., an absorption refrigerator not only requires the use of baskets, but also the adjustment of the wick).

**Reason for change:** In view of the increasing number of freeze-sensitive vaccines in immunization schedules and the problem of procedure compliance in the field, freeze protection during storage has become a priority. This grading will provide an indication on the level of user intervention required.

**Timing for PQS Inclusion:** 2015.

Gross volume of the vaccine storage compartment:

- The internal free volume, including the volume occupied by shelves, but excluding the space taken by the ice-lining or other type of thermal storage, if present. For square and rectangular compartments, capacity will be measured and published as volume in litres, and length, width and height in centimetres. Non-rectangular compartments will be measured and published as volume in litres, including maximum width or diameter, minimum width or diameter and height in centimetres.

Net vaccine storage capacity:

- The volume of the compartment allocated by the manufacturer for vaccine storage. For square and rectangular compartments, capacity will be measured and published as volume in litres and length, width and height in centimetres. Non-rectangular compartments will be measured and published as volume in litres including maximum width or diameter, minimum width or diameter and height in centimetres. The net vaccine storage capacity is obtained by loading the vaccine storage compartment up to the manufacturer's loading markings with boxes or blocks measuring 100x100x100 mm or 100x100x50 mm, packed so that there is a minimal air space between each column of packets or between the packets and any adjoining wall. If baskets are provided, load the boxes or blocks into the baskets in the same manner. The total volume of the dummy load, in litres, represents the net volume available for the storage of vaccines.
- The capacity of products which are supplied with racks or holders designed to retain individual vaccine vials and ampoules will be measured and published as the maximum number of primary containers (including vials and ampoules) that can be contained based on the standardized sample of vaccines.
  This sample of vials and ampoules is intended to represent the range of primary container sizes that users may insert into the vaccine storage compartment.
  For every 10 vaccine primary containers use a sample that includes the tallest, the widest and the most common diameter primary containers as specified below:
  Tallest: Quantity two (2) ampoules 1.07 x 9.25 cm (diameter x height ±5 %)
  Widest: Quantity two (2) vials 3.0 x 7.4 cm (diameter x height ± 5%)

Common: Quantity six (6) vials 1.7 x 5.3 cm (diameter x height ± 5%)

**Reason for change:** To provide manufacturers with storage capacity definitions that are consistent with existing WHO-produced cold box performance specifications.

**Timing for PQS Inclusion:** 2015

Primary container:

- Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.

**Reason for change:** To recognize and address the practise of storing individual vaccine vials and ampoules.

**Timing for PQS Inclusion:** 2015

## 4. Design criteria

*4.1 Vaccine storage capacity*

- Final capacity bands remain to be confirmed, but capacity within the [5 to 200] litre range has been proposed for discussion.

SDD equipment is typically deployed at the district store and health facility level where mains electrical supply is highly unreliable or unavailable. In order to meet the capacity needs at these two levels in the supply chain, whilst sending clear signals to industry, the public sector proposes to define additional net vaccine storage capacity bands.

**Reason:** To provide certainty for manufacturers and to simplify procurement decisions for countries. Specifically we wish to seek the views of manufacturers on the economic advantages of smaller units than those currently offered when compared with the possible use of long-term passive devices.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

*4.2 Water-pack freezing compartment*

- Both stand-alone freezers and combined refrigerators/freezers must be available.

The specifications for a stand-alone freezer will be developed in 2014. Additionally, a new methodology for estimation of ice production is currently being developed.

**Reason:** An SDD with a freezing compartment allows a health facility to provide outreach services and enables district level stores to provide coolant for vaccine transport. Initial first generation SDD refrigerators were not able to provide separate freezing capacity. This technical hurdle can and has been overcome.

In addition, district level SDDs with a freezing compartment would be able to service one or more long-term passive devices at their peripheral health facilities.

**Timing for PQS Inclusion:** 2015

*4.3 Temperature in vaccine storage compartment*

- The zone designated for vaccine storage must remain within the acceptable temperature range at all times. Surface temperatures within this zone must be no lower than [+1.5°C ±0.5°C]. Surfaces outside the vaccine storage compartment

may be at 0°C or below, provided there is no risk that this temperature can propagate into the vaccine storage compartment.

- Bulb and capillary tube thermostats will no longer be accepted in accordance with the next publication of WHO/PQS/E003/RF05 or RF06.

**Reason:** To eliminate the risk of vaccine coming into contact with freezing surfaces.

**Timing for PQS Inclusion:** 2015.

**Reason:** Field exposure of elevated temperatures have caused failure in some bulb and capillary tube thermostats.

**Timing for PQS Inclusion:** 2015.

*4.4 Humidity control*

- The environmental conditions within the zone designated for vaccine storage must be designed so that vaccine primary containers and vaccine cartons are not exposed to levels of humidity which may cause damage to cartons or primary container labels or create a risk of mould growth. These conditions must be maintained in operating environments where ambient humidity is [100%].
- Manufacturers are to propose containers for vaccine storage and/or refrigerator features to help alleviate humidity, such as installing a drain to remove water from the cabinet.

**Reason:** Instances have occurred where cartons and vials in SDDs have been damaged by exposure to excessive moisture.

**Timing for PQS Inclusion:** 2015.

*4.5 Design of vaccine storage compartment*

- The vaccine storage compartment must be designed so that no part, which is outside the acceptable temperature range can be used to store vaccines, either by inadvertent or deliberate misuse.
- As per the classification of freeze prevention features (section 3, Terms and definitions) appliances complying with this requirement without demanding any intervention from the user will be published as Grade A. Others will be published as Grade B or Grade C depending on the level of interventions required.

Further, the vaccine storage compartment must provide some means, such as baskets, to enforce physical separation between the vaccines and any surfaces that potentially have condensate on them, such as the floor, ceiling and/or walls of the compartment. Those are not optional but have to be provided.

**Reason:** Users in the field, for a variety of reasons, are likely to be unable to perform interventions necessary to protect vaccines from freezing in the refrigerator. For example, baskets may not always be used in a refrigerator in the field due to the desire to use all the available space in the vaccine compartment. Hence, the need for designs that are user-independent, and will ensure proper vaccine protection regardless of user behaviour. Manufacturers are encouraged to move towards Grade A user-independent freeze protection (UIFP) designs.

**Timing for PQS Inclusion:** 2015.

Some current products have removable baskets, which if not used, allow vaccines to be stored in areas which may drop below 0°C. This risk needs to be removed in second generation products.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

*4.6 Low ambient temperature operation*

- All SDDs must be able to operate at a continuous minimum ambient temperature of [+10.0°C or lower] whilst maintaining the acceptable temperature range. As an option, products may be offered which can operate at continuous ambient temperatures of 0°C or lower.

**Reason:** Some current products have a very narrow operating temperature range. Suitability for a wide range of ambient temperature conditions makes product selection, procurement and relocation simpler for countries, especially in countries with different climate zones or with pronounced summer and winter temperature ranges.

**Timing for PQS Inclusion:** 2015.

*4.7 Refrigerant*

- As specified in WHO/PQS/E003/RF05.3 and RF06.2 the WHO is proposing that future specifications require the use of HC refrigerants such as R600 or other gases with GWP ≤11 and zero ODP, while R134a will be phased out over a transition period of two years in accordance with the next publication of WHO/PQS/E003/RF05 or RF06. The suitability of alternative refrigerant gases will continue to be assessed.

**Reason:** To provide visibility to manufacturers into the WHO's future refrigerant specifications.

**Timing for PQS Inclusion:** 2015.

*4.8 Autonomy*

- As specified in WHO/PQS/E003/RF05.3 and RF06.2 as a minimum, with a preferred target of 5 days.
- Additionally, the product can operate in autonomy with a maximum solar radiation reference period of 3.5 kWh/m² day.

**Reason:** There are places where more than 3 days of autonomy is required.

**Timing for PQS Inclusion:** 2019, subject to change upon further discussions.

*4.9 Power source*

- Direct supply from a photovoltaic panel array. An ancillary power storage system (e.g., battery, capacitor) may be included provided it has a minimum guaranteed design life of 10 years under the environmental conditions for which the SDD will be prequalified (Hot zone, Temperate zone or Moderate zone as specified in WHO/PQS/E003/RF05.3 and RF06.2), and a charge level indicator.
- Because most SDD's can operate without ancillary batteries, the option for devices with ancillary batteries will phase out in a transition of two years in accordance with the next publication of WHO/PQS/E003/RF06.
- A system that is able to provide spare power for other facility electrical loads (e.g. rechargeable devices such as lighting units, temperature monitoring devices, and mobile phone charging) is acceptable provided the vaccine refrigerator is always

prioritized ahead of other power uses followed by freezing, ancillary devices and then other facility loads.

**Reason:** Ancillary power storage systems (e.g., battery or capacitors) must have the same design life as the product.

**Timing for PQS Inclusion:** 2015

**Reason:** There is increasing demand for solar power for other uses in health facilities. Next generation SDD power supply specifications need to acknowledge this requirement whilst assuring the priority need to keep vaccine within the acceptable temperature range.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

*4.10 Input voltage*

- Solar module voltage up to 45 volts open circuit (Voc) is acceptable provided all electrically powered system components are integrated in such a way that performance and component life is not reduced by voltage input from the solar array.

**Reason:** Compressors can utilize a range of input voltages including 30 to 36 volts now commonly available in solar modules that may have economic advantages owing to their very wide scale use with grid-connected systems. Higher input voltage may also reduce solar array cable costs and/or improve energy efficiency when compared to lower input voltage.

**Timing for PQS Inclusion:** 2015.

*4.11 Temperature monitoring*

- The refrigerator compartment must be equipped with a 30-day temperature logger device that supports the transfer of data to another system for analysis purposes. Acceptable options include the following:
  1. **Type 1:** A currently prequalified disposable 30 day temperature logger complying with WHO/PQS/E006/TR06.3, with or without an external sensor lead, located in an integrated holder within the vaccine storage compartment. The holder must be positioned so that the device can easily be read by the health worker, and must be located so that temperature readings are taken in the minimum temperature zone within the compartment.
  2. **Type 2:** If compatible with country systems, a fully integrated device, powered by photovoltaics, which complies with the performance requirements set out in WHO/PQS/E006/TR06.3: *30-day electronic refrigerator temperature logger*. The temperature calibration and power source for this device must have a guaranteed design life of at least [10 years] or there must be a simple arrangement for periodically installing a new pre-calibrated sensor head.
  3. **Type 3:** Either a Type 1 or Type 2 device, but enabled to send SMS alarm messages.

**Reason:** 30-day temperature recorders are now the WHO-recommended standard for temperature monitoring at all levels in the supply chain. It is important that the logging device's temperature sensor is consistently located in the refrigerator so that temperature readings accurately reflect the worst case temperature to which vaccines

are exposed. Existing PV-powered thermometers have shown mixed results in the field, with a significant incidence of failure.

**Timing for PQS Inclusion:**

**Type 1:** 2015.

**Type 2:** 2017, subject to change upon further discussions.

**Type 3:** 2019, subject to change upon further discussions.

*4.12 Performance degradation*

- Product design must account for performance degradation over the target life of the product in order to sustain acceptable vaccine storage temperatures, water pack freezing or cooling (if included) and other product features (if included).

**Reason:** Certain insulation materials and other components may degrade over time potentially impacting temperature control and energy consumption.

**Timing for PQS Inclusion:** 2015.

*4.13 User-centred design features*

- Advantages of chest appliances are known; however, it is to be recognized that front opening refrigerators are preferred at the health facility level. Therefore this option should be made available to this segment of the market.
- Products must be designed for simplified maintenance and troubleshooting, such that there is a minimum requirement for work by trained technicians, and should include a minimum number of components requiring service actions.

**Reason:** There are advantages with front opening refrigerators that need to be taken into consideration. Particularly at health facility level, vaccines are easier to handle and earliest-expiry-first-out (EEFO) principles can be practiced with greater simplicity. Front-opening refrigerators also offer more convenient access to the vaccine stock at health facility level where frequent access to individual primary containers is required.

Some current products are overly complex. This makes repair and maintenance difficult and error-prone.

**Timing for PQS Inclusion:** 2019, subject to change upon further discussions.

- In order to make efficient use of available storage space and to protect primary container labels against physical damage and moisture damage, the refrigerator compartment should be equipped with an adjustable system of racks, stackable boxes or drawers designed to hold primary containers in a secure manner. These storage devices must be designed to accommodate the full range of vial and ampoule sizes used for WHO-prequalified vaccines. In addition there must be provision for safe storage of vaccines in secondary cartons where these are supplied and also for storage of vaccines in other presentations such as compact pre-filled devices (e.g. Uniject™) and oral cholera vaccine.
- A standard for optional storage containers for vials and ampoules could be envisioned. This would lead to better organized contents and higher volume utilization in health facility refrigerators.

**Reason:** Vaccines are often removed from secondary cartons at district level and are supplied to smaller health facilities in primary containers. Frequently, a mix of

primary containers and cartons is observed. Current SDDs have no specific provision for storing loose vials and ampoules which leads to poor stock management, label damage and poor utilization of available storage volume. Although some countries resolve these problems by using plastic boxes and trays, these ad-hoc arrangements are unsatisfactory.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

- Non-vaccine cold chain products such as oxytocin are frequently stored in health facility refrigerators, especially in counties which have adopted health service integration. The storage containers described above should include components for holding these products. These components should be clearly distinguished from the components used for storing vaccines, either by colour or through the use of suitable markings. This is essential in order to limit the risk of medical error arising from administration of the wrong product.

**Reason:** Increased health service integration. See also previous bullet point.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

- Control panels and integrated thermometers must be able to present legible information to a reader at a standing position. For example, the product could make use of a larger and/or higher contrast LCD screen to enable better legibility.

**Reason:** In response to end users demand. Control panels close to floor level are inconvenient, even if the panel is tilted.

**Timing for PQS Inclusion:** 2017, subject to change upon further discussions.

- In addition to the PQS temperature zone sticker the device should carry the following additional information:
    - Near-Term: Manufacturer and model number (unless already located on the front of the unit), serial number, data of manufacture, PQS identification number, applicable service phone number, and website URL fixed to the front of the cabinet.
    - Near -Term: An operations and maintenance pictogram fixed to the lid or near the top front of chest refrigerators and near the top of the door on upright refrigerators.
    - Long-Term: The above information, plus a bar code to identify the fridge (actual definition of bar code TBD) fixed to the front of the cabinet.
- Given the large amount of information, it is expected that separate stickers could convey the totality of information.
- PQS stickers should be readable for the expected age of the equipment.

**Reason:** To simplify data gathering for in-country equipment inventories.

**Timing for PQS Inclusion:**

Near-Term: 2015.

Long-Term: 2019, subject to change upon further discussions.

*4.14 Build quality*

- The build quality of the product and all ancillary components must be to a standard consistent with the conditions under which these appliances are used, including, but not limited to, the following:
  1. Transport over rough road surfaces.
  2. High temperatures in transport and operation.
  3. Low temperatures in transport and operation.
  4. Operating locations with high wind and high density of dust particles.
  5. High humidity.

**Reason:** Specific issues noted with current prequalified refrigerators include: insufficient robustness to withstand transport; deformation of thermal storage components affecting use of the vaccine storage baskets; failure of bulb and capillary tube thermostats; poorly routed and retained wiring; component corrosion; and accessibility for service.

**Timing for PQS Inclusion:** 2015, note that with no specific standards this is communicated only as a goal.

*4.15 Service provision*

- The product must be designed, and components selected, with the aim of achieving a zero-repair life of not less than 10 years.
- Maintenance activities should be confined to tasks that can be carried out by the health worker or storekeeper; these tasks should be confined to routine de-frosting and cabinet cleaning and solar array cleaning. The installation kit provided for each site must include the specialized maintenance supplies and/or tools needed to carry out these routine tasks. Wherever possible, the means for routine maintenance should be built into the product: for example, a drainage tray or spout for defrosting.

**Reason:** Equipment breakdowns expose vaccines to risk and skilled maintenance staff are frequently not available in resource-poor settings.

**Timing for PQS Inclusion:** 2015.

*4.16 Instructions*

- Printed user and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information should be summarized on a single sheet fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the product and must be in a locally-understood language. In addition supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.
- Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the installation teams in installation standards and practices specific to the product and its power system.

**Reason:** High quality instructions are a pre-requisite for high quality installations and good routine maintenance. Increasingly, countries are using video instructions for training purposes.

**Timing for PQS Inclusion:** 2015.

*4.17 Shipping and storage conditions*

- Manufacturers must be aware that products may be exposed to very high temperatures during shipping and dockside storage and must take appropriate actions to mitigate this risk.

**Reason:** Instances have occurred where SDDs have been damaged during transit and storage due to exposure to high ambient temperatures in shipping containers.

**Timing for PQS Inclusion:** 2015.

*4.18 Accessories*

- Specialized tools and materials required for installation and/or required for technical maintenance are to be clearly identified to prospective buyers and offered as an option by the manufacturer.
- Accessories not required for regular operations and/or not required for routine user maintenance are to be offered as an option by the manufacturer.
- Items that are required for regular operation and routine maintenance are not considered accessories and must be included as standard with each appliance supplied.

**Reason:** Appliances have been provided without items required for regular operations and maintenance such as ice scrappers for defrosting and condensate catchment pans. These items and specialized installation tools and materials are not always readily available in the area of installation and additional funds may not be available for installer or user purchases.

**Timing for PQS Inclusion:** 2015.

*4.19 Spare parts*

- Attached within each refrigerator or combined refrigerator water pack freezer there must be a set of 10 spare fuses for each fuse size and type used.
- Manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 units.

The minimum spare parts for 10 refrigerators or combined refrigerator water pack freezer is:

1 no. compressor or complete cooling unit, to suit supplied refrigerators.

1 no. electronic unit (compressor control or cooling system control).

1 no. thermostat (or temperature control components).

1 no. canister R-600a x 100 grams, if used.

1 no. fan, if used.

**Reason:** Appliances have been provided without spare fuses and fuse types not always readily available in the area of installation. Spare parts can be assessed at time of purchase based on manufacturer specific requirements, country conditions, existing spare parts stocks and geographic distribution of installations.

**Timing for PQS Inclusion:** 2015.

| 5. Revision history | | | |
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| Date | Change summary | Reason for change | Approved |
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