General Concepts

Types of Health Commodities

“Health commodity” is a broad term that can refer to many items different in nature, and that may be needed for the provision of health services in humanitarian emergencies: scales, face masks, medicines, vaccines, preservatives, dressing material, alcohol used for medical procedures, needles and syringes, laboratory/diagnostic consumables, oxygen, etc. The sensitivity and stability of the product, the risks and the handling requirements, or the regulations for all these different items may be very diverse. The requirements for face masks or protective gloves are not the same as for medicines and vaccines so for an efficient and effective management of the supply chain, it’s important to know what products are being handled.

The most common terms used to define and categorise the types of health commodities are:

Medicine (Including vaccines)	Medicines can be defined as products including, but not limited to, finished pharmaceutical products, vaccines, and in vitro diagnostics (IVDs). A medicine is a substance or combination of substances that is intended to treat, prevent, or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological, or metabolic action. Medicines usually have requirements for some level of temperature control, are usually considered fragile goods and often have requirements to limit light and humidity exposure. Vaccines are a subset of medicine products and are usually extremely sensitive to high or/and low temperatures.
Medical Devices (Reusable and Consumable)	Medical devices can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. This includes reusable medical devices (stethoscopes, forceps, endoscopes, surgical instruments, etc.) and consumable devices (needles, syringes, sutures, gloves, etc.).
Hospital Equipment	Hospital equipment can be any equipment, machinery, computers, tools, vehicles, software, furniture, or other infrastructure component used within a hospital or health facility environment. Hospital equipment generally does not have a temperature requirement but some of which may be considered fragile and have special requirements for transport (e.g. sensitive electrical equipment).
Laboratory Equipment	Laboratory equipment can include any support equipment or analytical instrument necessary to or involved in generating the results of a medical analysis. Some laboratory equipment have requirements for temperature control, are usually considered fragile goods and may have special requirements for transport of electrical components.
Therapeutic Food	Generally, includes ready-to-use therapeutic food (RUTF) and therapeutic milks (F-75, F-100) which are used in emergency response to manage acute malnutrition. Therapeutic food is generally not included in essential list of medicines or in other applicable essential health commodity lists, and therefore doesn’t follow the same formal scrutiny as Medicinal Products. Although RUTF has been designed to resist harsh field conditions allowing management of malnutrition at community level, it always has an expiry date and exposure to high temperatures can accelerate the degradation mechanisms and reactions.

Packaging and Labelling

Packaging and labelling are integral parts of the medical products as it is where the specifications set by the manufacturer for handling and consumption are described, including the expiry date. Packaging of medical items serves to preserve the product from contact to the environment and its conditions. All printed material is considered part of the packaging and is registered as part of the regulatory requirements of the NDRA.

The product label should include the following information as appropriate:

- Name of the product
- Active ingredient(s), type and amount
- Batch number
- Expiry date
- Special storage conditions or handling precautions
- Directions for use, warnings and precautions
- Names and addresses of the manufacturer and/or supplier

The expiry date and storage conditions of pharmaceuticals and medical devices are determined by conducting stability studies to mimic different environments around the world, and by testing that medications still meet their expected quality control specifications after predetermined durations under those conditions. If a day/month/year is not printed as an expiration date, international best practice is that the item can be used up to and including the last day of the month mentioned.

Medicinal products are often packed and handled in several layers of packaging:

- **Primary packaging** – Primary packaging is in direct contact with the medicinal product, such as glass vial and rubber stopper, or blister foil. Primary packaging material is selected as part of the development process of a new medicine to assure its integrity, sterility (for injectable products) and to protect from humidity.
- **Secondary packaging** – Secondary packaging is the container into which the product in its primary packaging is placed to be delivered for distribution to healthcare workers. Often, this is a folding carton. For most medicines, a pack of a known quantity of the product defines a "unit" for stock keeping purposes. Secondary packaging generally protects the product from light, vibration and physical shock.
- **Tertiary packaging** – Tertiary packaging is the container(s) into which, for most medicines, a number of units are placed for transport. Often this is known as a shipper carton. Tertiary packaging may also include insulated or thermal shipping containers.

Packaging materials in medicines are usually referred to as primary or secondary, with the difference being only primary packaging is intended to be in direct contact with the product. Tertiary packaging is not considered as part of the product.

There are strict regulations on the way medical products should be packaged and labelled. In emergencies, there may be a programmatic or operational rationale for repackaging or kitting/de-kitting of health commodities:

- Repackaging when it involves primary or secondary packaging is a manufacturing operation subject to strict national and international regulation and should be performed only at authorised premises (e.g. sterile) under the responsibility of a qualified person, or upon receipt at the health facility.
- Kitting/de-kitting which involves taking multiple secondary packages and repacking into different tertiary packages, (if it does not involve breaking down secondary packaging), is not considered pharmaceutical repackaging and can be conducted at the warehouse level depending on the national regulatory framework.

Health kits, as they are made up of a mix of items, have some modifications related to packaging and labelling on the tertiary packaging:

- Itemised packing lists should be included inside of each kit box, outside of each kit box, and on the pallet the kit(s) are shipped/transported on, with at a minimum: Name of the product, qty, batch number, expiry date, special instructions.
- Health kits are labelled with the "first item to expire" within the entire kit (even if the kit is more than one box/pallet).
- Health kits often have a separate batch/Lot number which identifies the entire kit from the supplier.
- Health kits should be labelled with the total number of tertiary packing (e.g. carton boxes) per kit and indicate the number of that specific tertiary package out of the total (e.g. box 7/12).
- If shipping multiple health kits per pallet, pallet wrapping should indicate the total quantity of each specific health kit for ease of receipt and inspection.

When planning logistics operation, it is of key importance to know what level of packaging is being mentioned, and the number of units per pack size, as volume and weight per unit may vary considerably. Incomplete or inconsistent information in the packaging of a medical product must raise suspicions and must be duly reported.

Regulated Commodities and Traceability

Though the regulation in each country may vary, the national regulations are established to ensure that only authorised goods are supplied to the population, and that the goods are supplied end-to-end, with minimal impact on their quality, safety, and efficacy.

Traceability constitutes a continuous product identification system throughout the entire supply chain. Every stakeholder involved in the pharma distribution has the obligation to start up, apply and maintain an effective goods traceability system to guarantee that, in case of a product constituting a serious risk to human health, the product can be withdrawn from the market immediately. Clear identification of the products, including tracking product batch number throughout the whole supply chain is essential to safeguard traceability and enable item recall related reverse logistics. The principles of traceability help avoid the introduction of substandard or falsified (counterfeit) medicines into legitimate supply, as well as normalise which products are distributed and how.

As a best practice, all elements of distribution operations should be documented. Under local laws, all documentation pertaining to health items might be required to be made available for inspection by health authorities on request and may be required in the event of investigations or audits in the future.

Where national regulations are limited, or the urgency or the lack of resources do not allow surveillance of distribution activities, WHO provides generic guidelines for the storage and distribution of medical products that should be applicable where national regulations are limited, or resources or circumstances do not allow surveillance of distribution activities by local authorities.

Handling Requirements and Time and Temperature Sensitivity

Many medical items are classified as time-temperature sensitive products; products which lose efficacy, or may even become dangerous, depending on exposure to temperature conditions outside of the manufacturing guidelines. These items are called time and temperature

sensitive, as the usability of the product after an exposure depends on the length of time of the exposure and how severe of an exposure was documented. Nearly all pharmaceutical products, most consumable medical devices and IVDs, and many sensitive medical equipment are considered time-temperature sensitive.

To ensure quality, safety, and efficacy of the product, the specifications set by the manufacturer (for storage, transportation, and distribution) must be well known and respected. Manufacturers' specifications, such as the storage ranges for temperature and relative humidity, come from very specific stability studies meant to identify the limits of the medical items. Not managing the medical items within those ranges will lead to quality issues and may cause harm to patients. In addition, certain items are light sensitive and hence require appropriate packaging and avoidance of direct exposure to light to prevent item degrading or damage. Furthermore, the respect of handling requirements such as hygiene, avoiding degradation of the items, follow up of expiry dates and traceability are also often included in the legal requirements expressed by national regulatory authorities.

The most common temperature ranges used for handling of medical products are:

Temperature Range	Common Name
+15°C to +25°C	"Controlled ambient" or "Temperature-Controlled"
+8°C to +15°C	"Cool"
+2°C to +8°C	"Cold" or "Chilled" or "Refrigerated"
-25°C to -15°C	"Deep freeze" or "Frozen"
different ranges between -80°C to -40°C	"Ultra-low"

Terms like "ambient", "room temperature" and "cold chain" should be avoided when describing storage and handling needs as a whole, or when used as the only labelling for storage or transport of boxes/containers because these terms are not always clear and might have different meanings in different parts of the world. It is always better to indicate the temperature range to avoid confusion on the nomenclature when labelling goods or providing instructions for management considerations. General differences in nomenclature around the world might include:

Terminology	WHO	European Pharmacopoeia	US Pharmacopoeia	Japan Pharmacopoeia
Frozen/ deep-freeze	-20°C	>-15°C	-	-
Refrigerator	-	+2°C – +8°C	-	-
Cold	+2°C –+ 8°C	+8°C – +15°C	<+8°C	+1°C – +15°C
Cool	+8°C – +15°C	+8°C – +15°C	+8°C – +15°C	-
Room temperature	+15°C – +25°C	15°C – +25°C	temperature prevailing in a work area	+1°C – +30°C
Controlled room temperature	-	-	+20°C – +25°C excursions between +15°C and +30°C are allowed	-
Ambient temperature	+15°C – +25°C or +30°C depending on climatic conditions	-	-	-

Adapted from ECA Academy "Regulatory Definitions for "Ambient", "Room Temperature" and "Cold Chain"

Storage conditions are always better explicitly specified in terms of a defined temperature range (e.g., +15°C to +25°C or +2°C to +8°C). Particular attention should be given to avoiding freezing of liquids and semi-solids.

It is a common regulatory expectation to keep track of temperatures at which products have been stored. Keeping records of expiry dates and batch numbers is also a GDP requirement.

Set Point – A set point is a term that is frequently used in both storage and transport of temperature regulated items. A set point is defined as the temperature at which a powered refrigerated storage or transport container is configured to keep the goods in the desired temperature range. A set point of +5°C is often used in appliances for storage or transport between +2°C to +8°C, letting +/- 3 degrees C of margin before experiencing a temperature deviation.

Temperature Monitoring – Monitoring of health times refers to the manual or automatic method of monitoring and tracing the temperature environment of health items while in storage or in transit. There are a variety of monitoring techniques and equipment, and their use will depend on the nature of the transported goods, the local infrastructure, and monitoring requirements put in place by national authorities.

Temperature Excursions

A temperature excursion is defined as any deviation from pre-defined specific temperature range for a product during storage, transport, or handling. Temperature excursions can be

caused by faulty equipment not regulating temperature, improperly set equipment, or items being handled transported or stored under inappropriate conditions. Excursions can be caused by relatively simple things, such as a door to a refrigerated container being left open for too long during loading or unloading, or a vehicle being parked in a sunny spot. Generally, temperature excursions are informed by temperature monitoring equipment that log the extent or duration of the excursion, however even without monitoring equipment excursions can be noted using common sense, such as identifying temperature regulated cargo left in the sun.

The response to an excursion depends on the severity of the excursion, and on the nature of the impacted goods. Routine basic pharmaceuticals that experience a temporary excursion may not require extra special attention, while refrigerated vaccines exposed to the same excursion may be considered completely unusable. In the event of an excursion:

- The personnel transporting or managing storage of the temperature regulated health items should take note of the excursion, and make a physical written record as required by your agencies protocol.
- The senior logistics or supply chain manager should be notified, who will need to take the appropriate action within your organisation's rules and regulations for quality risk management:
    - A quality assurance specialist or focal point may need to be sent the documents which outline the deviation (e.g. datalogger information) to advise on the usability of the product and/or instructions.
    - Depending on the end use of the items, the ultimate consignee might need to be notified of any temperature excursions along the supply chain.
    - In some contexts, local or national health authorities might need to be notified of any temperature excursions.
    - The staff pharmacist or health program manager may need to be notified to take appropriate actions.

In severe cases, agencies may need to contact the manufacturers of the health items to understand how to best handle the situation.

- The cause of any temperature deviation should be documented, and mitigation measures should be implemented immediately to avoid future damages to additional products.

In the event that a temperature deviation results in an unusable product the logistics or supply chain personnel may need to dispose of the item in line with national medical waste management protocols. This may involve reverse logistics.