MDS-G25

Guidance on Requirements for Storage, Handling and Transportation of Medical Devices

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Introduction

Purpose

The purpose of this guidance is to clarify requirements of the storage, handling and/or transportation of medical devices.

Scope

This guidance applies to establishments (importers, distributors, local manufacturers involved in distribution activities, or ARs involved in importation and/or distribution activities) involved in the storage, handling and/or transportation of medical devices within the KSA.

This guidance does not apply to healthcare providers. However, "Guidance for Healthcare Providers for Storage, Handling and Transportation of Medical Devices (MDS-G17)" provides recommendations to healthcare providers to ensure medical devices are properly stored, transported and handled to guarantee their safety and effectiveness.

Background

SFDA/MDS has issued this guidance document in reference to the following:

- Article fifteen of the "Medical Devices Interim Regulation" that requires that establishments involved in the importation and/or the distribution of medical devices within the KSA shall have an MDEL.
- Article Sixteen (B and C) of the "Medical Devices Interim Regulation" that requires from establishments involved in the importation and/or distribution of medical devices to ensure that medical devices are stored and/or transported under conditions specified by the manufacturer; and ensure traceability of devices it supplies to the market.
- Articles five and ten of "Implementing Rule on Establishment Licensing (MDS-IR4)" that indicates that the purpose of MDEL is to ensure that establishments are able and committed to undertake the procedures specified by the manufacturer for storage, transportation, handling and tracing the medical devices they import and/or distribute.

Requirements

Storage Area	1	Establishments shall have a storage area that: - is designed or adapted for the storage of medical devices - is clean and dry - is provided with thermometers. The thermometers shall be placed to allow effective monitoring where temperatures are most likely to fluctuate or rise, if applicable. - has surfaces and shelves, if applicable, made of or covered by an impermeable material to enable proper and safe cleaning. - is suitably spaced to allow cleaning and inspection - is adequately lit - is adequately ventilated - is set up with an emergency plan to be used in case of an electricity shutdown (power outage), if applicable, see Annex (2). - includes a physically separate area for keeping damaged, expired or recalled medical devices. This area shall be clearly labeled and controlled to prevent the use of these devices until a final decision is taken on their fate. Other means of segregation shall be considered if proven to effectively prevent mix-up. - is licensed by the Ministry of Municipal and Rural Affairs.
Traceability in the Storage Area	2	In case of a recall by the manufacturer or the SFDA, the establishment shall be able to trace a medical device in the storage area by its lot/batch/serial number and be able to specify the quantity still available in the storage area of a given lot/batch/serial number. For an example on traceability record, see Annex (1).
	3	Establishments shall monitor the expiry dates of medical devices in the storage area through periodic inventories to avoid unintended dispatch of expired devices, if applicable.
Transportation Vehicles	4	Establishments shall ensure that the vehicle used to transport medical devices are properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates. And shall used vehicle indicating in Annex (2). Uncoverd vehicle shall not be used at all.
Manufacturer's Instructions	5	Establishments shall store, handle and transport their medical devices under conditions specified by the manufacturer's instructions to prevent deterioration. These conditions might be related to one or more of the following:

		- temperature (all the medical devices shall be kept during storage and/or transportation at temperature ranges specified by the manufacturer). - moister and humidity. - exposure to light. - the direction the package should face. - the maximum number of packages stacked above each other. Notes: - If the label does not include information about the required storage and transportation conditions of a medical device, establishments are responsible for obtaining such information. - If the manufacturer does not specify the temperature range, Annex (2) specifies the temperature ranges of temperature instructions on labels. - If the manufacturer requires medical devices to be stored or transported under certain conditions (e.g. temperature and humidity), establishments shall monitor and periodically record these conditions. Such records shall be available for review.
Sterile Medical Devices	6	In addition to manufacturer-specific instructions and if the medical device is dispatched in a sterile state, establishments shall store, handle and transport it in a manner that protects its packaging from: - exposure to moisture. - direct sun-light. - damage. - dirt and non-clean environment. to ensure they are still sterile when received by the customer. Sterile medical devices shall be considered unsterile if packaging loses its integrity.
Staff	7	Staff involved in the storage, handling and transport of medical devices shall: - have appropriate knowledge about these activities. - be able to deal with medical devices that have different storage and transportation requirements, if applicable.
Written Procedures	8	Establishments shall have a written procedure that describes the practices taken to ensure that the medical devices are stored, handled, and transported based on the manufacturer's instructions. For more details about writing procedures, see Annex (3).

Annexes

Annex (1): Example of Traceability Record

#	Medical Devices Name	Manfucturer Name	Lot#/ Batch#/ Serial Number# Catalogue#	Customer Information	Expiry Date	Quantity	Remaining Quantity	
							Quantity	Location
1								
2								
3								
4								
5								
.								
.								
.								

Annex (2): Interpretations for Temperature Ranges Provided on Labels

Instructions on Label	Temperature Range	Storage Area		Transporation (Vehicle)
		Cooling System	Backup Generator	
Stored in Freezer	means kept in temperatures between -20 and -10 °c	Freezer	Yes	Refrigerated
Stored in Refrigerator	means kept in temperatures between 2 and 8 °c	Refrigerator	Yes	Refrigerated
Stored in Cold place	means kept in temperatures does not exceed 8 °c	Refrigerator	Yes	Refrigerated
Stored in Cool place	means kept in temperatures between 8 and 15 °c	Air-conditioned	Yes	Air-conditioned
Stored in Room temperature	means kept in temperatures between 15 and 30 °c	Air-conditioned	Yes	Air-conditioned
Stored in Warm place	means kept in temperatures between 30 and 40 °c	-	No	Coverd
Avoid Excessive heat	means temperature should not exceed 40 °c	-	No	Coverd
Do not store over 30 °c	means to store within the range from +2 to +30 °c	Air-conditioned	Yes	Air-conditioned
Do not store over 25 °c	means to store within the range from +2 to +25 °c	Air-conditioned	Yes	Air-conditioned
Do not store over 15 °c	means to store within the range from +2 to +15 °c	Air-conditioned	Yes	Air-conditioned
Do not store over 8 °c	means to store within the range from +2 to +8 °c	Refrigerator	Yes	Refrigerated
Do not store below 8 °c	means to store within the range from +8 to +25 °c	Air-conditioned		Air-conditioned
Protect from humidity/ moisture	means to protect it from conditions where humidity exceeds 60%, and should be kept in a humidity resistant container	Depending on the Product Type		
Protect from light	means that should be stored in places not exposed to light. It should be kept in light proof containers	Depending on the Product Type		

Annex (3): Written Procedure

The written procedure of storage, transportation and handling the medical devices should:

- ideally be part of a quality management system and include the records and controls such a system requires;
- identify a member of staff responsible for ensuring the manufacturer's instructions for the storage, handling and transport of its medical devices are identified and properly implemented; and that all personnel involved in such activities have the appropriate experience and training to undertake the duties assigned to them;
- identify the range of different requirements and accommodate them all within the procedure, where the establishment imports or distributes medical devices from more than one manufacturer,;
- provide evidence that the medical devices are stored apart from other goods and under conditions complying with the manufacturer's instructions, in particular, concerning ambient humidity, temperature and light requirements;
- ensure that storage and transport conditions, including those in the receiving bay, will prevent damage, deterioration or other adverse effects of the medical devices pending their distribution; and are properly monitored and, where appropriate, recorded;
- specify the action to be taken in the event of deviations from the required storage or transport conditions;
- describe the storage area, and the method used to include a secure area(s) within it for the purpose of storing separately:
    - any quarantined medical devices or, where necessary
    - devices incorporating dangerous and/or hazardous substances;
- incorporate a system to ensure the medical device inventory is properly rotated (i.e. either 'first in …… first out' or 'expiration date' driven) and that any device exceeding its expiry date, or shelf life, is quarantined;
- incorporate a procedure to quarantine medical devices subject to a recall and/or field safety corrective action or to identify non-defective devices that have been returned from a user or other organization from other inventory until a decision on further action has been reached in cooperation with the manufacturer;
- ensure that medical devices are properly packed, handled and stored for transportation as well as transported in a suitably vehicle, taking into account the manufacturer's instructions with respect to temperature, humidity, vibrations and the risk of physical damage. Ensure that these factors are properly monitored and, where appropriate, recorded during transportation.
- indicate the used vehicles for transportation from the port of entry to the storage area/warehouse and from the warehouse to the customer, if applicable. And indicate Transporter company, if applicable.

Annex (4): Required Documents for Quality Assurance Purposes

(including violation of requirements of storage, handling and transportation of medical devices)

	Required Documents	Notes
1	License from the Ministry of Municipal and Rural Affairs	-
2	MDEL	-
3	AR License	• If applicable
4	MDMA or Medical Device Listing National Registry Number Issued by MDNR System	• Applicable for all medical devices in the storage area
5	Shipment Clearance Letters (Issued at SFDA's Port of Entries)	-
6	IFU Accompany Medical Device	• Applicable for all medical devices in the storage area • It shall be in Arabic if the user of the medical device is a lay person (Home Use Medical Devices)
7	Quality Management System (QMS) Certificate	• If applicable
8	Writing Procedures	-
9	Traceability Documentation	• It may be in electronic format
10	Records for Storage Conditions (e.g. Temperature and Humidity)	• If applicable
11	Record for Recalled and/or Damaged Medical Devices	• If applicable
12	Records for Disposed of Medical Devices	-
13	Qualifications of Employees	-
14	Purchase Invoices for Local Agents and Clients	-

Annex (5): Checklist of Violation for Quality Assurance Purposes

(including violation of requirements of storage, handling and transportation of medical devices)

#	Violation
1	No MDEL Available
2	The MDEL is not valid or renewed
3	The establishment did not update the their information in the MDNR
4	The establishment did not list all their medical devices in the MDNR
5	The establishment's information supplied to the MDEL are not conform with the real onsite information
6	Establishment did not apply for MDMA
7	Establishment used unapproved advertisement material
8	Establishment is unable to provide copy of sales or services employees' qualification.
9	Sales employees have sufficient knowledge on the medical devices they market
10	Applied traceability methods are not sufficient or not effective
11	Absence of a written procedures for transportation, installation or maintenance
12	Written procedures for transportation, installation or maintenance is not implemented by establishment.
13	Current practice of transportation , installation or maintenance does not meet the manufacturer's instructions
14	Absence of a written procedure for storage and handling of medical devices
15	Absence of storage area of medical devices
16	Storage area is not licensed by Ministry of Municipal and Rural Affair
17	Absence of emergency plan for the storage of medical devices in case of an electricity shutdown (power storage)
18	Procedure for storage and handling of medical devices is not implemented
19	Storage area is not clean/dry
20	Storage area is not suitably spaced to allow cleaning and inspection
21	Absence of storage shelves (medical devices are are placed on floor)
22	Surfaces/Shelves are made of permeable material which prevents appropriate cleaning
23	Storage area is not adequately illuminated
24	Storage area is not adequately ventilated
25	Storage conditions (e.g. temperature, humidity) are not effectively monitored

26	Parameter related to the required storage conditions are not recorded
27	Thermometers are not appropriately placed to allow effective monitoring
28	Storage, transportation and handling requirements are not appropriately communicated to staff performing these tasks
29	Storage and handling practices are not appropriate for sterile medical devices
30	Absence of separate storage area for damaged, expired and recalled medical devices
31	Establishment does not monitor expiry dates of medical devices including IVDs in the warehouse
32	Establishment does not keep records of the disposal of medical devices
33	Establishment does not comply with manufacturer's storage, transportation and handling instructions
34	Medical devices are not accompanied by the appropriate labeling
35	Establishment has expired, damaged or used medical devices
36	Establishment has counterfeit medical devices.
37	Establishment has home-use medical devices without Arabic instructions
38	Not applying corrective actions on non-conformities in previous inspection reports
39	Non-conformities in the inspection report
40	Absence of a valid AR license issued by SFDA to include all medical devices
41	The lack of a status legal representative after the end of representation license
42	The AR agreement is not legalized: (1. Chamber of commerce, 2. Foreign Affair Ministry, 3. Saudi Embassy in manufacturer's country, 4. Foreign Affair Ministry in manufacturer's country)
43	Absence of a written procedure for reporting medical devices adverse events
44	Procedure for reporting medical devices adverse events is not effective
45	Absence of a written procedure for implementing corrective action required for field safety notices
46	No registration in the NCMDR

Annex (6): Common Mistakes

- Staff involved in the storage, handling and transport of medical devices are unaware of appropriate procedures for these activities, not informed of existence of written procedures or the written procedure are not accessible for them.

- The stored medical devices are not well organized or aligned to facilitate inspection and cleaning process.

- There is no written procedures for storing, transporting and handling of medical devices.

- Not following the written procedures of storing transporting and handling of medical devices.

- There is no emergency plan to be used in case of an electricity shutdown (power outage) in the storage area, if applicable.

- There is no a physically separate area for keeping damaged, expired or recalled medical devices.

- Parameters related to the required storage conditions are not recorded and monitored, if applicable.

Annex (7): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Establishment	any place of business within the KSA that is involved in the manufacture, and/or placing on the market, and/or distribution of medical devices; or acting on behalf of the manufacturer.
Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Medical Devices National Registry (MDNR)	the database of both registered establishments and medical devices the SFDA has authorized to be placed on the KSA market.
MDEL	Medical Devices Establishment License
MDMA	Medical Devices Marketing Authorization