FDA CIRCULAR
No. _____

SUBJECT: **Good Storage and Distribution Practices for Medical Devices**

I. RATIONALE

Good storage and distribution of medical devices are vital in maintaining the quality of medical devices from the supplier to the end user of the product. It is essential that establishments ensure that medical devices are protected from various risks that will adversely affect the quality of these products during the various stages in the supply chain such as purchasing, storage, distribution, transportation and delivery, installation, servicing and maintenance.

Department of Health Administrative Order No. 2020-0017 entitled "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003" provides that all establishments shall provide the appropriate storage condition to maintain the safety and quality of health products. Aside from providing appropriate storage condition, it is equally important that distribution including delivery, transportation, installation, servicing and maintenance are managed appropriately to ensure the quality and performance of medical devices when used by the intended end-users.

Pursuant to the provisions of Implementing Rules and Regulations of Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009" the functions, powers and duties of the FDA include the development and issuance of policies, standards, regulations, and guidelines that would cover establishments, facilities and health products including medical devices to ensure the safety, quality and efficacy of these products in the market.

In the interest of service and to ensure the quality, safety and performance of medical device during the various points in the supply chain of these health products, this Circular is hereby issued for guidance of all concerned.

II. OBJECTIVE

This Circular aims to specify the requirements for good storage and distribution practices for medical devices which will serve as guide for medical device establishments engaged in the manufacture, importation, distribution and selling of medical devices in the Philippines.

III. SCOPE

These guidelines shall apply to manufacturers, traders, distributors (exporters/importers/wholesalers) and retailers responsible for the supply of medical devices to another medical device establishments, healthcare facilities, patients or end-users of medical devices.

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the meaning as defined in R.A. 9711 and its implementing rules and regulations, Administrative Order (AO) No. 2020-0017 and related laws and regulations. However, for clarity and for purposes of these guidelines, the following terms are defined as follows:

A. **First expiry/first out** – refers to a procedure that ensures that the stock with the earliest expiry date is distributed or sold before an identical stock item with a later expiry date is distributed or sold.

B. **First in/first out** – refers to a procedure in which the first items to come into the establishment/warehouse are the first items to be distributed or sold.

C. **Good distribution and storage practices** – refers to the part of quality assurance that ensures that the quality of medical device products is maintained by means of adequate control throughout the storage thereof and throughout the numerous activities which occur during the distribution process.

D. **Marketing authorization holder (MAH)** - refers to the medical device company, corporate or legal entity in whose name the Certificate of Product Registration (CPR), Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) for a medical device has been granted. The MAH is responsible for all aspects of the product, including quality and compliance with the conditions of the issued CPR/CMDR/CMDN. The MAH may be a manufacturer, trader, or distributor (exporter, importer or wholesaler) of medical devices.

E. **Medical Device** – any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in intended function by such means.

F. **Supplier** – refers to a manufacturer, trader, or distributor (importer/wholesaler/exporter) that is engaged in the activity of providing medical device products.

G. **Vermin** – refers to a group of insect or small animals such as flies, mosquitoes, cockroaches, lice, bedbugs, mice and rats which are vectors of diseases

V. GUIDELINES

A. RECORDS

1. Records shall be kept for each purchase and sale of medical device showing the following details specified below:
   a. For manufacturer
      i. Date of purchase
      ii. Name of medical device
      iii. Model number (if applicable)
      iv. Batch/Lot number (if applicable)
      v. Expiration date (if applicable)
      vi. Specification of product (if applicable)
      vii. Quantity distributed/sold
      viii. Distribution records
      ix. CPR/CMDR/CMDN of the product
      x. Records of full documentation of the registration of the product submitted during registration/notification

   b. Distributor (exporter/importer/wholesaler)
      i. Date of purchase
      ii. Name of medical device
      iii. Model number (if applicable)
      iv. Batch/Lot number (if applicable)
      v. Expiration date (if applicable)
      vi. Specification of product (if applicable)
      vii. Quantity received and sold
      viii. Name of licensed supplier
      ix. Copies of valid LTO of licensed supplier
      x. Notarized MOA/Contract with supplier /distribution agreement (if applicable)
      xi. Importation and distribution records
      xii. Copies of CPR/CMDR/CMDN of the product
      xiii. ISO certificate for the foreign supplier (manufacturer) or GMP certification for local manufacturers
      xiv. Records of full documentation of the registration of the product submitted during registration/notification

c. Retailer
    i. Date of purchase
    ii. Name of medical device
    iii. Model number (if applicable)
    iv. Batch/Lot number (if applicable)
    v. Expiration date (if applicable)
    vi. Specification of product (if applicable)
    vii. Quantity received and sold
    viii. Name of licensed supplier
    ix. Copies of valid LTO of licensed supplier
    x. Copies of CPR/CMDR/CMDN of the product

2. Records shall be kept for as long as the medical device product is registered with the FDA.
3. Records shall show traceability of the origin.
4. Proof of delivery transactions shall be kept.
5. There shall be an orderly and secure system of filing up to date invoices from suppliers and buyer.
6. Records shall be easily retrievable, stored and protected against unauthorized modification, damage, and/or loss of documentation.
7. The establishment shall keep records of laws, policies and latest issuances relative to the regulation of medical devices.
8. If the records are generated and kept in electronic form, there shall be backups to prevent any accidental data loss.

B. STANDARD OPERATING PROCEDURES

The establishments shall have standard operating procedures for the following activities:

1. Procurement of products
2. Release of products
3. Transportation / shipment of products including investigation in cases of failure to comply with storage requirement during transit (if applicable)
4. Maintenance of vehicle and equipment
5. Storage of stocks including temperature monitoring and retention of monitoring records (if applicable)
6. Handling of complaints - a distinction should be made between complaints about a product or its packaging and those relating to distribution
7. Handling of return of medical devices.
8. Handling of product recall including storage and final disposition of recalled products.
9. Destruction of medical device (expired, damaged, unusable stocks)
10. Handling of medical device products at the port/s of entry (if importer)
11. Self-inspection to monitor implementation and compliance with the principles of this guideline and, if necessary, corrective and preventive measures.

C. PERSONNEL

1. Responsibility and Authority

Establishment shall have an organizational chart and documented job descriptions, including key responsibilities and authorities.

2. Training and Competency

Key personnel in charge including those in the warehousing operations shall possess the necessary competence in terms of education, training, skills and experience. Training may include proper handling, use and operation of the device, as applicable, warehouse management and inventory.

D. PREMISES

1. Cleanliness

a. Premises shall be kept clean.
b. A written sanitation program shall be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
c. There shall be no smoking, eating and drinking in areas where medical devices are stored and handled.

2. Vermin Control

a. The storage area shall be designed and equipped to prevent entry of vermin and other animals into the area
b. There shall be a written vermin control program to prevent vermin infestation. Appropriate records shall be kept for this purpose.

E. RECEIPT, STORAGE, STOCK HANDLING AND DELIVERY TO CUSTOMERS

1. Receipt of stocks

a. The receiving area shall be adequate and shall have protection for deliveries from bad weather during unloading.
b. It shall be separate from the storage area.
c. Each incoming delivery shall be checked to ensure that the correct product is delivered from the correct supplier. This may include checking of the purchase order, containers, label description, batch number, expiry date, product and quantity.
d. The delivery shall be examined for uniformity of the containers and, if necessary, shall be subdivided according to the supplier's batch number should the delivery comprise more than one batch.
e. Each container shall be carefully checked for possible contamination, tampering and damage. Any suspect containers or, if necessary, the entire delivery shall be quarantined for further investigation.

f. Medical devices subject to specific storage measures shall be immediately identified and stored in accordance with the specified instruction(s).
g. Measures shall be taken to ensure that rejected medical devices cannot be used. They shall be segregated and securely stored while awaiting destruction or return to the supplier.

2. **Storage**
   a. Precautions shall be taken to prevent unauthorized persons from entering storage areas.
   b. Storage areas shall be of sufficient capacity to allow the orderly storage of the different categories of medical devices.
   c. There shall be adequate lighting and ventilation.
   d. Storage areas shall be maintained within acceptable and specified temperature limits. The storage conditions for medical devices shall be in accordance with their labelling.
   e. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these shall be provided, controlled, monitored and recorded. Temperature of the storage areas shall be measured at suitable predetermined intervals to show the maximum and minimum temperatures for the day and recorded. The equipment used for monitoring shall be calibrated and be suitable for their intended use. Calibration shall be traceable to applicable international/national standard and the calibration records shall be maintained.
   f. Medical devices shall be stored off the floor and suitably spaced to allow cleaning and inspection. If pallets are used, such shall be well maintained and kept clean at all times.
   g. Medical devices shall be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.
   h. Appropriate and suitable storage conditions shall be provided for hazardous, sensitive and dangerous materials such as combustible liquids and solids, pressurized gases, highly toxic and radioactive substances.
   i. There shall be designated areas for quarantined, saleable stock, expired, rejected/damaged, recalled and returned medical devices. Such medical devices shall be properly labeled.
   j. A list of medical devices shall be maintained and the medical devices properly identified.

3. **Stock Control and Rotation**
   a. Periodic stock reconciliation shall be performed at defined intervals by comparing the actual and recorded stock. The root cause for stock discrepancies shall be identified and appropriate corrective and preventive action taken to prevent recurrence.
   b. Stock shall be appropriately rotated. The “first expiry/first out” principle shall be followed. For cases where the medical devices do not have expiry dates, “first in/first out” shall be applied. If there is a manufacturing date, the product with the earlier manufacturing date shall be first to be released.
   c. All stock shall be checked regularly to identify obsolete and expired stock.

d. Medical devices with broken seals, damaged packaging or suspected tampering/contamination shall not be sold.
e. Medical devices bearing an expiry date shall not be sold close to the expiry date such that the expiry date is likely to occur before the consumer uses the medical devices. Expired medical devices shall not be distributed or sold to consumers.
f. All labels and containers of medical devices shall not be altered, tampered or changed.
g. If the name and address of the Marketing Authorization Holder (MAH) and the CPR/CMDR.CMDN of the medical device are not indicated on the product's label, the MAH shall affix a sticker on the label indicating the said mandatory labeling requirements on the medical device pursuant to the provisions of Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements".

4. **Delivery to Customers**
   a. Medical products shall be transported in accordance with the conditions stated on the labels. There shall be no risk to the quality of the medical devices during transport and delivery.
   b. Delivery vehicles shall be suitable for their purpose, with sufficient space and appropriately equipped to protect the products.
   c. When the medical device is intended solely for professional use, such medical device shall be sold to the indicated type of user or to customers with medical prescription only.

F. INSTALLATIONS AND SERVICING

1. Where installation and servicing of a medical equipment are required, these shall be conducted by competent or trained personnel.
2. Installation, inspection, any required testing and/or servicing shall be performed in accordance with the manufacturer's instructions and procedures.
3. The establishment shall maintain records of inspection and any test results to demonstrate proper installation of the medical equipment. Records of servicing shall likewise be maintained.

G. MEDICAL DEVICE COMPLAINTS

1. The establishment shall have a record for each individual complaint.
   The records on complaints may include the following information:
   a. the medical device brand name, CPR/CMDR/CMDN number, model/catalogue number or bar code, control/serial/ lot number and any other means of identification of the medical device;
   b. the name(s) and address(es) of the supplier;
   c. records pertaining to the problem investigation.
2. The record shall show that the complaints received are investigated and followed through, and that corrective actions are taken to prevent repeated complaints and,

where a decision is made to recall the product, the details of the recall.

3. There shall be a designated personnel to handle complaints.
4. The written standard operating procedures for handling of complaints shall identify the designated personnel and describe his/her functions and responsibilities. The procedure shall contain the following:
   a. determination of whether there is a health hazard associated with the medical device;
   b. determination of whether the medical device fails to conform to any claim made by the dealer relating to its effectiveness, benefits, performance characteristics or safety;
   c. determination of whether the medical device fails to meet any regulatory requirements
   d. determination of the most appropriate preventive/corrective action;
   e. justification when no action is taken, for example, in the case of receiving an unfounded or invalid complaint.
5. Complaint records maintained with respect to a medical device should be retained for a period of five (5) years on top of the projected useful life of the medical device as determined by the product owner. For example, if the projected useful life of the medical device is one year, the complaint records should be kept for six years.

H. RETURN OF MEDICAL DEVICES

1. There shall be standard operating procedures for handling of return of medical devices.
2. There shall be a record for returned medical device products.
3. All returned medical devices shall be kept separate from saleable stock until a decision has been reached regarding their disposal.
4. Returned medical devices shall be re-evaluated and can be returned to saleable stock provided the products have met the following criteria as applicable:
   a. the medical devices are in their original unopened containers and in good condition;
   b. it is known that the medical devices have been stored and handled under proper conditions;
   c. the remaining shelf life period is acceptable; and
   d. the medical devices have been examined and assessed by appropriate personnel. The assessment shall take into account the nature of the medical device, any special storage conditions required, and the time that has elapsed since it was distributed. Special attention shall be given to thermolabile medical devices. Advice shall be sought from the product owner as necessary.

I. DISPOSAL OF MEDICAL DEVICES

1. Medical devices that are expired, contaminated, damaged or defective or found to be counterfeit shall be disposed of properly in accordance with applicable government rules and regulations (e.g. FDA Circular No. 2016-012 entitled "Guidelines on Product Recall")

2. The establishment shall ensure that the medical devices for disposal will not be sold.
3. The disposal shall be properly recorded and such records shall be maintained by the establishment.

J. RECALLED, COUNTERFEIT, ADULTERATED, TAMPERED, BANNED, PHASED-OUT, UNUSABLE MEDICAL DEVICES

1. Any recalled, counterfeit, adulterated, tampered, banned, phased-out or unusable medical devices shall be physically segregated and stored separately from other medical devices. For recalled products, the establishment shall comply with FDA Circular No. 2016-012 entitled "Guidelines for Product Recall".
2. These medical devices shall be labeled as "Not for Sale" for easy identification and guidance of the personnel.
3. There shall be a designated personnel to handle recalled, counterfeit, adulterated, tampered, banned, phased-out or unusable medical devices.
4. The establishment shall inform the Food and Drug Administration – Center for Device Regulation, Radiation Health, and Research, the supplier (manufacturer/trader/distributor) or the product owner immediately regarding the recalled, counterfeit, banned, adulterated or tampered medical device product.

VI. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this FDA circular shall be imposed after notice and hearing following Book III Uniform Rules of Procedures or in accordance with Book II, Article I, Section 4. Grounds for Disapproval of Application and Suspension or Cancellation of License, Registration, or Authorization provided in the Implementing Rules and Regulations of RA 9711.

VII. SEPARABILITY CLAUSE

In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

VIII. TRANSITORY PROVISION

All existing licensed medical device establishment prior to the issuance of this Circular shall be given a period of two (2) years from the effectivity of this Circular to comply with the provisions thereof.

IX. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center - Office of the National Administrative Register.

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Secretary of Health

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