



SOP FOR NEAR EXPIRY DRUGS



VMMC & Safdarjung Hospital,
Ministry of Health & Family Welfare,
Government of India, New Delhi.



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Document No.	TITLE		
SJH/ NABH/ Policy/ 28	SOP for near expiry and expiry medicines		
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Distribution: Quality Cell, Medical Superintendent, All Head of Departments, OIC, Drug store, OPD Pharmacy, officiating nursing officer, All wards, ICUs, procurement section, Nodal office, VMMC & Safdarjung Website

REVISION SUMMARY

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1.0	29/03/2021	00

SOPs on near expiry and expiry drugs

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Procedure for maintaining near expiry drugs at stores and pharmacy

1.1 Purpose

To establish a procedure for identifying, handling and maintaining the near-expiry medications in Drug stores, departmental sub-store and Pharmacy (OPD) with a view to minimize loss and ensure patient safety.

1.2 Scope

All the important activities related to handling of near expiry drugs in the VMMC & Safdarjung Hospital.

1.3 Responsibility

- OIC drug store
- Pharmacist in-charge of Drug store
- Sister in-charge of various departments of the hospital.
- Pharmacist in-charge of Pharmacy (OPD).

1.4 Procedure

1.4.1 All drugs delivered to the hospital must carry an "Expiry date" which must be recorded in the stock register by Pharmacist in-charge of Drug Store.

1.4.2 At the time of reception of drugs by the concerned department and Pharmacy (OPD), Expiry date of drugs must be checked by the Pharmacist in-charge /Nursing sister in-charge of various sub-stores of the Safdarjung hospital.

1.4.3 Pharmacist, nurse will check expiry drug before dispensing or medication administration and if found drug near expiry and or expired will immediate initiate action mentioned in policy.

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1.4.3 The Drug Store, Pharmacy (OPD) and all other department sub-stores must follow **First in-First out (FIFO)** system of inventory management to minimize the stock of near expiry drugs, except incases where the stock received later have a shorter expiry date.

1.4.4 Store, Pharmacy (OPD) and department sub-store in-charges must arrange the drugs which will expire in next **3 months**, on separate shelves.

1.4.5 All efforts must be made by concerned Pharmacist in-charge, Nursing sister in-charges of all departmental sub-stores to see that drugs found to be of near expiry can be transported to other departments i.e. intra & inter departments for utilization of the drugs within their expiry date.

1.4.6 If near expiry drugs are not in a position to be consumed, in that way they should be sent to Store.

1.4.7 If the item is urgently needed and there is no replacement stock in Pharmacy (OPD) and Store then the Nursing sister in-charge can use it until last day of expiry.

1.4.8 When the near expiry drugs are received at Store then the officer in-charge Store must be informed about the near expiry drugs who in turn may explore either of the following:-

- Inter-departmental transfer
- Drug replacement from the manufacturer / supplier for fresh stock

It is advisable to procure, install and use a **Hospital Management Information System (HMIS)** having proven efficiency to minimize the loss to the Government exchequer due to expiry of drugs. This will also be useful in identifying, at the click of a button, the drugs which are approaching their date of expiry so that they can be got replaced from the manufacturer/supplier or can be consumed within the Hospital to avoid wastage.

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1.2 Records

- Near Expiry stock of drugs must be recorded in the stock register of the particular department, ward or Pharmacy as the case may be.

1.3 Process efficiency criteria

- The number of drugs nearing expiry must be minimal and should show a declining trend with time.

1.4 Activity

- **Monthly inspections** must be conducted by the concerned pharmacist and nursing staff of respective departments.
- **Quarterly review** by the DTC to assess the number of drugs reaching near expiry and actions taken thereof during the year

1.5 References

- Drugs & Cosmetics Act, 1940.
- Drugs & Cosmetics Rules, 1945.
- The Pharmacy Act, 1948.

1.6 Definitions

- **Expiry Date** means the date that is recorded on the container, label, or wrapper as the date up to which the substance may be expected to retain a potency not less than or not to acquire a toxicity greater than that required or permitted by the prescribed test. **The date of expiry of a product as assigned by the manufacturer is at times expressed only in month and year, which means that the product is to be used until the last day of the given month for that year.**
- **Near-expiry Drugs** refers to drugs, the efficacy of which is about to lapse **within 3 months from the expiry date** printed on the label by its manufacturer.

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2. Procedure for disposal of expired drugs

2.1 Purpose

To establish a procedure for the segregation and disposal of expired drugs in hospital.

2.2 Scope

All activities required for disposal of expired drugs in the hospital.

2.3 Responsibility

- Officer in-charge drug store
- Pharmacist in-charge drug store
- Officer in-charge Pharmacy (OPD),
- Pharmacist in-charge Pharmacy (OPD)
- Officer in-charge of Unit/ward
- Nursing Sister in-charge of Unit/ward
- DTC
- Officer in-charge Bio-Medical Waste Management of Hospital

2.4 Procedure

2.4.1 All the expired drugs from various areas/departments should be returned to drug store of the hospital with proper documentation.

2.4.2 The information about expired medicines must be recorded in a separate register for expired drugs. The following particulars are to be documented.

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- Name of drug (Generic/brand)
- Formulation (Tablet/Capsule/Syrup/ Ointment/Injection etc.)
- Strength
- Batch number
- Expiry date
- Total quantity
- Name of the department

2.4.3 At the Store the expired drugs must be received by the Pharmacist in-charge. He must verify the details and the drugs record as given below.

2.4.4 All expired drugs should be stored preferably in a separate room ear marked for the purpose. In the absence of a separate room the expired drugs may be stored in a separate cupboard. The cupboard must always be under lock and key with a sign board on it stating “Expired drugs not for use”. The room / cupboard must be under supervision of Officer in- charge/ Pharmacist in-charge of MDS.

2.4.5 The Officer in-charge Store will inform the DTC about the details of the expired drugs for their disposal.

2.4.6 After approval from DTC the Officer in-charge Store will inform the Medical superintendent, about the list of expired drugs to be sent for disposal to Bio- Medical Waste In-charge or return to manufacturer/supplier.

2.4.7 The Officer in-charge Store will send this list to return to manufacturer/supplier or hospital Bio-Medical Waste in-charge for disposal as per rules.

2.4.8 All the expired drugs must be transported in pilfer proof containers/boxes properly labeled and sealed in accordance with prevailing Bio-Medical Waste Management Rules.

The hospital DTC will regularly meet and assess the list of expired drugs and reasons for the same.

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2.5 Records

- Expiry drug register in sub-stores of Store/unit/wards/ ICU/OT/departments.
- Expiry drug register in Pharmacy (OPD)
- Expiry drug register at Store.
- Drug disposal register at Bio-Medical Waste Management Department.

2.6 Process Efficiency Criteria

- The number of expired drugs in a hospital should ideally be nil or minimal.
- Within a hospital the number of expired drugs annually must decrease over time.

2.7 Activity

- Review of expired drugs by DTC at regular interval (at least quarterly).

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Form for list of expired drugs and label for disposal

1) List of expired drugs

S. No.	Name	Formulation*	Strength	Batch No.	Expiry Date	Quantity	Name of Department, Unit, Ward etc.	Unit/Ward No.

*Formulations include dosage form.

Signature of Officer In-charge store/Unit/Ward/ICU/OT/OPD Pharmacy/NEB/SIC/SSB

Signature of Nursing Sister In-charge of store/Unit/Ward/ICU/OT/OPD

Pharmacy/NEB/SIC/SSB

Stamp

2) Label for transfer of expired drug

Date.....

Category of drug.....

Bio-hazard symbol.....

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3) BIO MEDICAL WASTE CATEGORIES

SCHEDULE I

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category Type of Waste Type of Bag or Container to be used Treatment and Disposal options (1) (2) (3)

Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
1	2	3
<p>(A) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.</p>	<p>Yellow colore dnon-chlorinated plastic bags or containers</p>	<p>Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200°C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200°C Or</p> <p>Encapsulation or PlasmaPyrolysis at >1200°C.</p> <p>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.</p>

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LABEL FOR

BIO-MEDICAL WASTE CONTAINERS or BAGS

CYTOTOXIC HAZARD SYMBOL



HANDLE WITH CARE

HANDLE WITH CARE

Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day

Month

Year

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Date of generation

Waste category Number

Waste quantity.....

Sender's Name and Address Receiver's Name and Address:

Phone Number

Phone Number

Fax Number.....

Fax Number

Contact Person

Contact Person

In case of emergency please contact:

Name and Address:

Phone No.

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