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केंद्रीय भेषजी
Central Pharmacy
अखिल भारतीय आयुर्विज्ञान संस्थान, रायपुर (छत्तीसगढ़)
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All India Institute of Medical Sciences, Raipur,
Chhattisgarh.

(An autonomous premier institute under Ministry of Health & Family Welfare
Government of India under Pradhan Mantri Swasthya Suraksha Vojna-PMSSY)

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Document No.	TITLE		
AIIMS/Raipur/ Policy/01	Standard Operating Procedure (SOP) for near expiry and expiry drugs.		
Effective date:	23.08.2021		
Function	Name	Designation	Signature with seal
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Distribution: Deputy Director (Administration), Administrative Office, Medical Superintendent, All Head of Departments, Office In Charge (OIC), Central Pharmacy D-Block, Drug store, Out Patient Department (OPD) Pharmacy, officiating nursing officer, All wards, Intensive Care Units (ICUs), procurement section, AIIMS Raipur website (IT department.)

Revision Summary		
Version Number	Effective date	Revision History
1.0	23/08/2021

Annexure for Abbreviations

PMSSY	Pradhan Mantri Swasthya Suraksha Yojna
AIIMS	All India Institute Of Medical Sciences
VMMC	Vardhman Mahavir Medical College
DTC	Drug and Therapeutic Committee
DMS	Deputy Medical Superintendent
FIP	Faculty In charge Pharmacy
SOP	Standard Operating Procedure
CEO	Chief Executive Officer
OIC	Office In Charge
OPD	Out Patient Departement
ICUs	Intensive Care Units
OT	Operation Theater
IT	Information Technology
ANS	Assistant Nursing Superintendent
SNO	Senior Nursing Officer
NO	Nursing Officer
FIFO	First In First Out
FEFO	First Expiry First Out
T&E	Trauma & Emergency

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Procedure for maintaining near expiry drugs at Central Pharmacy stores and wards across the hospital.

1.1. Purpose

To establish a procedure for identifying, handling and maintaining the near-expiry medications in Central Pharmacy D-Block, 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 All India Institute of Medical Sciences, Raipur.

1.3 Responsibility

- Faculty in-charge Pharmacy/Office In Charge (OIC) drug Pharmacy
- Pharmacist in charge of Central Pharmacy, Drug store
- Assistant Nursing Superintendent (ANS)/Nursing Superintendent (NS)/Senior Nursing Officer (SNO)/ Nursing Officer (NO) 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 Store keeper/Pharmacist in-charge of Central Pharmacy, Drug Store.

1.4.2 At the time of reception of drugs by the Central Pharmacy, concerned department and Pharmacy (OPD), Expiry 'date of drugs must be checked by the Receiving end/Pharmacist in-charge / ANS/SNO/NO of various sub- stores of the All India Institute of Medical Sciences, Raipur.

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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.

1.4.4 The Central Pharmacy, 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 in cases where the stock received later have a shorter expiry date. If the stock received by Pharmacy or wards is short expiry than First Expiry First Out (FEFO) must be followed.

1.4.5 Central Pharmacy, Store, Pharmacy (OPD) and department sub-store in-charges must arrange the drugs which will expire in next 3 months, on separate shelves/areas with label.

1.4.6 All efforts must be made by concerned Pharmacist in-charge, ANS/SNO/NO/ 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 with in their expiry date.

1.4.6 If near expiry drugs are not in a position to be consumed, in that way they may be sent to State with approval of competent authority AIIMS Raipur.

1.4.7 If the item is urgently needed and there is no replacement stock in Central Pharmacy and Sub Store then the nursing/ANS/SNO/NO/ in-charge can use it until last day of expiry.

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

- Intra and Inter-departmental transfer
- Drug replacement from the manufacturer/ supplier for fresh stock
- Distribution in OPDs/Clinics/camps organized on time to time basis

As Hospital Management Information System (HMIS) having proven efficiency to minimize the loss to the Government exchequer due to expiry of drugs, hence Central Pharmacy is also using the same. This is also useful in identifying, at the click of a button, the drugs which are approaching their date of expiry so that they may be got replaced from the manufacturer/supplier or may be consumed within the Hospital to avoid wastage.

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 ANS/SNO/NO/ staff of respective departments.

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- **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.
- AIIMS Raipur storage policy/VMMC & Safdarjung Hospital

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 three months from the expiry date** printed on the label by its manufacturer.

2. Procedure for disposal of expired drugs

2.1 Purpose

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

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2.2 Scope

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

2.3 Responsibility

- Faculty in-charge/Officer in-charge Central Pharmacy, drug store
- Pharmacist in-charge drug store
- Officer in-charge Pharmacy (OPD),
- Pharmacist in-charge Pharmacy (OPD).
- Officer in-charge of Unit/ward
- Nursing ANS/SNO/NO/ in-charge of Unit/ward
- DTC
- Office In-charge Bio-Medical Waste Management of Hospital

2.4 Procedure

2.4.1 All the expired drugs from various areas/departments should be brought to the notice of DTC committee through proper channel and as per approval of the committee further management may be done with proper documentation.

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

- Name of drug (Generic/brand)

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

2.4.3 At the Store/wards the expired drugs must be segregated/ received by the Pharmacist in-charge/ward in charge. He/she 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 Faculty in charge Pharmacy/Officer in- charge/ Pharmacist in-charge of Central Pharmacy.

2.4.5 The Faculty in charge Pharmacy/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.

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2.4.8 All the expired drugs must be transported in pilfer proof containers/boxes/Yellow bag 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.

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	Unit/ Ward No.

*Formulations include dosage form.

Signature of Officer In-charge store/Unit/Ward/ICU/OT/OPD Pharmacy/T&E/Ayush/Covid/Office

Signature of ANS/SNO/NO/ In-charge of store/Unit/Ward/ICU/OT/OPD

Pharmacy/Store

Stamp

2) Label for transfer of expired drug

Date:

Category of drug

Bio-hazard symbol

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BIO MEDICAL WASTE CATEGORIES

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	(a) Human Anatomical Waste: Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	(b) Animal Anatomical Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.		
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or recovery.

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	<p>(d) 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 coloured non-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 $>1200^{\circ}\text{C}$ or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at $>1200^{\circ}\text{C}$ Or Encapsulation or Plasma Pyrolysis at $>1200^{\circ}\text{C}$.</p> <p>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.</p>
	<p>(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.</p>	<p>Yellow coloured containers or non-chlorinated plastic bags</p>	<p>Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.</p>
	<p>(f) Chemical Liquid Waste : Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.</p>	<p>Separate collection system leading to effluent treatment system</p>	<p>After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule-III.</p>
	<p>(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.</p>	<p>Non-chlorinated yellow plastic bags or suitable packing material</p>	<p>Non-chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery.</p> <p>In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.</p>

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	(h) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of micro- organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.
Red	Contaminated Waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and <i>fixed needle syringes</i>) and vaccutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

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LABEL FOR

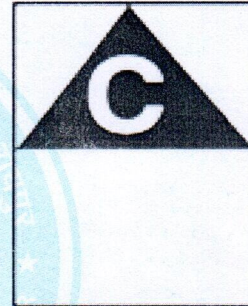
BIO-MEDICAL WASTE CONTAINERS or BAGS

CYTOTOXIC HAZARD SYMBOL

CAUTION**BIOHAZARD**

CYTOTOXIC HAZARD SYMBOL

कोषिकाविष परिसंकेत चिन्ह

**CYTOTOXIC**

कोषिकाविष

HANDLE WITH CARE

आरोग्यम् सुखं सम्पदा

HANDLE WITH CARE

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Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day

Month

Year

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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