SIKKIM
GOVERNMENT GAZETTE

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GOVERNMENT OF SIKKIM
DEPARTMENT OF HEALTH CARE, HUMAN SERVICES AND FAMILY WELFARE
TASHILING SECRETARIAT, GANGTOK

No. 751 / HC - HS & FW/ 2017 Dated : 26 . 07. 2017

NOTIFICATION

Whereas, it is deemed expedient to have guidelines to facilitate the proper condemnation and disposal of all expired and not of Standard Quality Drugs in the State of Sikkim;

And Whereas, a committee is deemed expedient for proper implementation of the procedures while disposing such articles/ materials in accordance to the prescribed guidelines so framed;

Therefore, the State Government is hereby pleased to prescribe procedures within the scope as prescribed herein and be called as the " Guidelines on Drugs Disposal Procedures as categorized here under and also constitute the 'Condemnation Committees' at various levels in the Health Care,Human Services & Family Welfare Department, as given below;

I. Introduction
II. Classification
III. Categories
IV. Procedures
V. Members of the Committee

I. Introduction

1. The purpose of disposal is to remove the expired, defective drug or a drug which represents an undue health risk to the patients.

2. Any communication received or an observation which states or implies that there is dissatisfaction in purity, efficacy, labeling, safety, physical appearances, quantity shall be considered as defect or adverse event/experience.

3. On receipt of the complaint regarding product defect, the course of action shall be decided as per the outcome of the investigation. If required, the product recall shall be initiated and the drug may be disposed, thereafter.

4. The source of complaint/observation shall be but not limited to: -

(i) Internal observation during routine sample review.

(ii) External source like sample report after sample drawn by any competent authorities,healthcare professionals and patients.

II. Classification

Class – 1 Critical defects.

(i) Declared sub-standard by Government lab or any adverse reaction observed after administration.
(ii) Product labeled with incorrect name or incorrect strength.
(iii) Counterfeit or deliberately tampered product.
(iv) Product mix-up
(v) Foreign materials like hair, metallic particle, rubber particles, etc.
(vi) Adverse drug event

Class – 2 Major defects.

(i) Labeling/leaflet misinformation or lack of information which represents a significant hazard to the patient health.
(ii) Illegible printing or overprinting, etc.
(iii) Broken or soft tablet in packet.
(iv)Spoiled packing materials during transit to an extent which can compromise the quality of the product.

Class – 3 Minor defects.

(i) Readily visible isolated packaging/closure faults.
(ii) Empty pocket
(iii)Contamination which may cause spoilage or dirty and where there is minimal risk to the patient.
(iv)Improper outer packing covers, Shipper information, etc.
(v) Dents/damage.

(Assessment of the reported defects, 'Acceptable Quality Level' may be used).

III. Categories

As per the available quantity, it shall be divided into three categories:-

1. Very small quantities
2. Small quantities
3. Large quantities

For category 1. If the quantity is very less (less than 50 tablets/10 bottles)

Step (i) : After de - packing/stripping, opening, tablets/liquids shall be flushed in the toilet. The remaining outer cover like strips or bottle may be properly discarded.

Step (ii) : Tablets/capsules after de-packing/stripping may be mixed with undesirable substances such as used tea leaves/ mud etc., (making less appealing and unrecognizable to the people who may intentionally go to the trash seeking drugs). Then place the mixture in a sealable bag and discarded properly.

For category 2. If quantity is less than 500 tablets/100 bottles,after stripping/ de-packing the tablets/ capsules/ syrups shall be dumped in the dumping yard (a small area outside the hospital shall be earmarked for dumping of medicines by burying underground.

For category 3. If quantity is less than 1000 tablets/500 bottles

The wholly packed tablet/ capsule after de-packing/ de-stripping, the tablets and capsules may be collected in double polybag packed and sent to the Central Health Store. Medicines like inhalers, syrups may also be sent to the Central Health Store for disposal.Medicines like inhalers , syrups may also be sent to the Central Health Store for proper disposal.

IV. Procedures

1. There is a policy for expired medicine take back purchased with a proper cash memo,

2. If the medicine has been sourced from Central Health Store then it shall be disposed as per the classification/category.

After receipt of the drug/medicine by the Central Health Store, Drug Disposal Committee shall request nearby Pharmaceutical Companies to allow use of their Effluent Treatment Plants (ETPs) as per the Plant' s Standard Operating Procedures (SOPs) and further transport the waste to Haldia, West Bengal.

A. <u>For Blister & Strip Packed Tablets & Capsules:</u>

(i) Use hand gloves and mask.
(ii) The cartoon/catch cover shall be de - packed & content shall be de - foiled & collected in double layer poly bags.
(iii) The cartoon catch cover shall be destroyed by shredding.
(iv) Transfer polybags containing tablets and capsules to nearby ETP.

B. Contaminated glassware/Large Volume Parenteral:

(i) Wear latex gloves and disposal mask.
(ii) Collect all contaminated materials like ampoules, vials, tubes in a disposal bag and put disposable bag into the autoclave.
(iii) Run the autoclave for 30 minutes
(iv) After completion of autoclave cycle, the liquid material shall be collected in plastic bin and then transfer it to nearby ETP.
(v) After drainage, crush the glassware in crusher & discard in garbage.

V. Members of the Committee

The following shall be the members at various levels of Committee:

1. The State Level Committee:

i.	Drugs Controller	Chairman
ii.	Representative, Sikkim Pollution Control Board	Member Representative,
	Sanitation Cell, Health Department	Member
iii.	Accounts Officer, Health Department	Member
iv.	Senior Drugs Inspector	Member
v.	Additional Director, Central Health Store Office	Member Secretary

2. STNM

i. AMS	Chairman
ii. Nursing Superintendent	Member
iii. Accounts Officer	Member
iv. Under Secretary	Member
v. S.O	Member Secretary

3. The District Level Committee

i. Chief Medical Officer	Chairman
ii. Accounts Officer	Member
iii.ANS/DNS	Member
iv.Medical Stores Officer	Member
v.District Medical Superintendent	Member Secretary

4. The Primary Health Centre Level Committee:

i. Medical Officer In-charge	Chairman
ii.Community Health Officer/Lady Health Visitor	Member
iii.Store In-charge/Store Keeper	Member Secretary

The terms of reference of the committees shall be as under:

(i) Meetings of the Condemnation Committees shall be held as and when required.
(ii) The Committees shall :-

a) Submit details of articles for condemnation and

b) Propose for condemnation to the State Level Committee.

By Order.

SD/-
(DR. KUMAR BHANDARI), MD, DM
Director General-cum-Secretary,
Department of Health Care, HS & FW,
Government of Sikkim.

Copy to:

01. All above concerned
02. Joint Director, I.T. Department : for hoisting in the official website
03. Deputy Secretary, Home Department : for publication in the official gazette
04. File &
05. Guard File

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Addl. Secretary to the Government,
Department of Health Care, HS & FW,
Government of Sikkim.