1. Purpose

This SOP provides the detail procedure (initiation, analysis, review, classification of defect, notice publication, recall of product and audit) for recall of medicines and medical products available in Nepali market as prescribed in section 14 of Drug Act 1978. The medicines or medical products that are not safe for consumption due to compromise in quality, safety and efficacy parameter or due to higher maximum retail price than approved by the Department of Drug Administration (DDA) are recalled following this procedure.

2. Scope

This SOP is applicable for statutory recall of medicines and medical products including human blood or blood component, biologicals, radiopharmaceuticals, health technology products not meeting the approved parameters for quality, safety, efficacy and cost. This helps ensure the effective recall of the product from market by the manufacturer or authorized distributor after recall notice issued by DDA for products failing to meet the pre specified standards and/or conditions.

Voluntary recall by manufacturer or distributor as per the provision of recall in section 10, 11 and 12 of chapter 7 in Codes on Good Manufacturing Practice (GMP) 2072 is the responsibility of manufacturer or authorized distributor and not considered in this SOP.

3. Responsibility:

SN	Designation	Responsibility
1	**Inspector**	a. Collection of product sample from market as per the sampling SOP. b. Submission of the samples along with relevant sampling details to the Department
2	**Monitoring, Evaluation and Law Enforcement Division**	a. Forwarding the product sample for testing to National Medicine Laboratory or other research center, laboratory, hospital or clinic and follow-up for the results.

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Pharmacy Officer	Senior Drug Administrator	Director General
Signature:	Signature:	Signature:

		b. Upon receival of the analytical report having non-compliance result, reviewing the risk type of the test results and forwarding for recall notification or other relevant decision on the products failing to meet the prespecified standards specification for approval from Director General. c. Issue a letter to the manufacturer or authorized distributor for recall. d. Follow up periodically to ensure effective recall of the product under consideration from the market.
3.	**Planning, Coordination and Management Division**	a. Forwarding the product sample for testing to National Medicine Laboratory. b. Upon receival of the analytical report having non-compliance result, the analytical report is forwarded to Monitoring, Evaluation and Law Enforcement Division for further regulatory action. c. Issuance of recall notice.
4.	**National Medicine Laboratory/ approved/recognized laboratory**	Testing of the products sample(s) as per specification to determine the quality, safety and efficacy parameters received from the Department and issuing the certificate of analysis of the product(s).
5.	**Director General**	Approval of recall order/notification

4. Procedure:

4.1 Collection and transportation of product sample

Samples of product available in market is collected by the inspector(s) designated by the DDA on any of the following basis:

a. Random sample collected during inspection process.
b. Complaint lodged to the department from consumers.
c. Post marketing surveillance sample.

Required quantity and volume of samples as prescribed or determined by NML/testing laboratory should be collected to analyze at least for two times. If required quantity of sample is not available, Inspector may take available quantity of sample considering the fact that collected sample is sufficient for limited or most important parameter to be tested.

Except in an event of basis a) and b) above the remaining shelf life of the samples collected should not be less than 6 months at the time collection.

The inspector collecting the inspection sample should collect the sample as per provision mentioned in Drug Investigation and Inspection Rules, 2040 (1983).

The inspector collecting the post marketing surveillance sample should collect the sample as per the PMS Guideline/PMS Working Document. However if the Department deemed necessary to be tested or analyzed from other than NML may send to listed research center(s), laboratory(ies), hospital(s) or clinic(s). Detail information of sample with parameter to be tested should be provided along with the sample to laboratory.

4.2 Analysis of sample

Laboratory should provide the analytical report in a prescribed form in Drug Investigation and Inspection Rules, 2040 (1983) along with certificate of analysis to DDA within time. Samples collected by NML as a part of its post marketing monitoring exercise can be considered as regulatory samples for this purpose.

4.3 Review of data and initiation of recall

Based upon the product failure report received from the National Medicines Laboratory or other testing laboratory, the inspection division reviews the report and categorizes the level of recall as class I/II/III as mentioned in *Annex-I classification of recall*.

4.4 Issuance of recall Notice

A recall notice is issued through official notice board and/or official website and/or national daily as prescribed in *Annex-II Recall notice*. The detail data of product recall is compiled and published on quarterly basis in Drug Bulletin of Nepal.

In addition to the process mentioned above, a recall notice is issued for following cases,

a. Import, distribution, storage, transportation and sale of prohibited drugs as per section 25 of the Drug Act.
b. False and misleading labeling and promotional advertisement materials in medicines or medical products violating the provision of Drug Act.
c. Products for which licenses (manufacturing and/or marketing) are suspended/cancelled from DDA.

A formal letter along with the copy of certificate of analysis of the product failing to meet the specification will be sent to the manufacturer or authorized importer/distributor for recall of the product by letter/ e-mail.

4.5 Manufacturer or Authorized distributor's responsibility

4.5.1 Recalls of medicines or medical products from market

The authorized person from the manufacturer or importer is responsible to stop the distribution, sale and use of the faulty medicine/ medical product as soon as possible. He/she should initiate the recalls process for such product from the market as defined in manufacturer's recall protocol. The procedure of recall should ensure complete recall of the product from the market up to the level of end consumers.

For Class I recalls, the sale, distribution and consumption of products should be stopped within **24 hours**. All products should be returned to the manufacturer or authorized importer/distributor within **7 days** of initiation of the recall process.

For Class II and Class III recalls, the process should be completed within **15 and 30 days respectively** after the initiation of the process.

The manufacturer or the authorized distributor shall act as appropriate to minimize the risk of the faulty products through public awareness campaigns like newspaper, radio, television or social sites.

The **details** of recalls should be maintained as product recalls logbook as per *Annex III-Logbook of Product Recalls.*

4.5.2 Reporting of recalls to the Department

A formal report with details of product dispatched to market and total units recalled from all **distribution** channels should be submitted to the Department **within 15 days** after completion of recall procedure. The report of recall should exhibit the effectiveness of the recall process to retract all products from the market. Inspectors from the Department upon receipt of recall report form the manufacturer or distributor may inspect the manufacturing or distribution facility or may ask to intimate the availability of product in market, consumption and stocks on hand as required.

4.5.3 Root cause analysis of product failure and recall

The **manufacturer** should commence a root cause analysis of the issue after recall of product or in parallel to the process. The control sample or real time stability sample of the same product should be analyzed and reviewed. This analysis will assist to assess the ongoing compliance of the product with regulatory requirements under the life-cycle approach. The root cause analysis along with corrective and preventive action on failure should be documented.

4.5.4 Fate of recalled product and reporting to the Department

The **recalled** product should be stored under lock and key until the fate of product is determined by authorized person on basis of evidence from root cause analysis.

Products not meeting the specification of quality, safety and efficacy should be destroyed according to approved procedure of the manufacturer.

Total units of medicines or medical products destroyed along with the procedure and person responsible for destruction should be maintained in destruction note. The destruction note for such incident should be recorded and approved by authorized person.

Alternate actions can be taken for recalled products meeting the quality and safety specification but that should comply the labeling requirements. Root cause analysis in such instances should be providing sufficient justification of reworks for recalled products. The expiry date of such reworked products should be the same as assigned previously. Reconciliation shall be done for the quantity dispatched of the batch under recall and quantity received after the recall is completed.

A written notice describing the procedure performed to the recalled product should be submitted to the department **within 3 months** of initiation of recall.

Annex-I: Classification of recalls

Class **I recalls** occur when products are potentially life-threatening or could cause a serious risk to health. This is for dangerous or defective products that the use or exposure to the product cause serious adverse consequences to health including death. The decision to make an urgent recall should be taken.

Examples of Class I Defects:

- Wrong product (label and contents are different)
- Correct product but wrong strength, with serious medical consequences
- Microbial contamination of sterile injection or ophthalmic product
- Chemical contamination with serious medical consequences
- Mix up of some products with more than one container involved.
- Wrong active ingredient in a multi-component product with serious medical consequences

Class II recalls occur when products are found to be defective or substandard, and use or exposure to the product might cause a temporary, medically reversible adverse health consequences, illness or mistreatment but the probability of serious adverse health consequences (life threatening/death) is remote and do not pose a health risk and are not class I defects.

Examples of Class II Defects

- Mislabeling e.g., wrong or missing text or figures
- Missing or incorrect information – leaflets or inserts.
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences

- Chemical/physical contamination (significant impurities, cross contamination, particulates).
- Mix up of products in containers.
- Non-compliance with specification (e.g., dissolution, assay, stability, fill/weight).
- Insecure closure with serious medical consequences (e.g. cytotoxic, potent products).
- Physical and visual deterioration like significant discoloration, sedimentation and crystallization.

Class III recalls occur when use and exposure to the defective product is unlikely to cause any adverse health consequences or may not pose a significant hazard to health, but that violate labeling or manufacturing regulations.

Examples of Class III Defects:

- Faulty packaging e.g., wrong or missing batch number or expiry date.
- Faulty closure
- Contamination – microbial spoilage, dirt or detritus, particulate matter.
- missing, broken or chipped tablets, improper embossing, cross label and or any physical defect.

Annex-II Recall Notice

नेपाल सरकार
स्वास्थ्य तथा जनसंख्या मन्त्रालय
औषधि व्यवस्था बिभागको

औषधि फिर्ता (Recall) गर्ने सम्बन्धी अत्यन्त जरुरी सूचना

प्रकाशित मितिः

रिकल वर्गीकरण : वर्ग (क)/ वर्ग (ख)/ वर्ग (ग)

यस विभागबाट बजार अनुगमनको क्रममा संकलन गरिएका औषधिहरुको नमूना परीक्षण गर्दा तपसिल बमोजिमको उत्पादकबाट उत्पादित तपसिलको ब्याच न. को औषधि न्यून गुणस्तर भएको पाइएकोले सो औषधि औषधि ऐन २०३५ को दफा १४ बमोजिम बिक्रि वितरण रोक्का गरी बजारबाट तुरुन्त फिर्ता (Recall) गर्न र सोको विवरण यस विभागमा पेश गर्न सम्बन्धित उद्योग/ तथा सम्बन्धित उद्योगको अधिकारिक आयातकर्ता तथा तिनका प्रतिनिधिहरुको जानकारीको लागि यो सूचना प्रकाशित गरिएको छ । साथै उक्त औषधि सिफारिस, बिक्रि वितरण तथा प्रयोग समेत नगर्न र नगराउनु हुन सम्बन्धित सबैलाई अनुरोध छ ।

तपसिल:

सि.न.	औषधिको नाम	ब्याच. न.	Mfg./Exp. Date	कारण	उत्पादकको नाम र ठेगाना

Annex-III Logbook of Product Recalls

S. No.	Name of the product	Dosage form	Manufacturer	Batch No	Mfg Date	Expiry Date	Report No.	Reason for Non-compliance	Published Date	Remarks