DRAFT VERSION

GUIDELINES ON RECALL AND RAPID ALERT SYSTEM FOR DRUGS

(Including Biologicals & Vaccines)

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Notification

The following draft guidelines is hereby published as required for NRA assessment by WHO. Objections or suggestions, if any may be addressed to the, Drugs Controller General (India), Central Drugs Standards Control Organisation, FDA Bhawan, New Delhi – 110002. or email id. dci@nic.in, whonra@yahoo.com, before the expiry of a period of fifteen days from the date on which publishing on the website.

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Central Drugs Standard Control Organisation

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1.0 Introduction:

Recall is an action taken to withdraw/remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality, efficacy or safety. The defective products related to quality include not of standard quality, adulterated or spurious drugs. Safety and efficacy related recalls include serious adverse reactions and death. Recalls also include drugs prohibited under the Provisions of Drugs & Cosmetics Act and also those products for which product licenses are suspended/cancelled.

Rapid Alert System is to transmit only those alerts whose urgency and seriousness cannot permit any delay in transmission. Assessment must be made of the seriousness of the defect, its potential for causing harm to the patient or (in case of veterinary product) harm to animals, consumers, operators and the environment.

2.0 Background:

In the Drugs & Cosmetics Act & Rules, there is a reference for product recalls, complaint and adverse reactions in Para 27 & 28 of Schedule M and also conditions of license for defective product recall in Rule 74(j) and Rule 78(i), but effective and uniform recall procedure, with time lines at every level of supply chain is required and at present auditing and accountability is not in place. This has been observed in instances where drugs declared as not of standard quality by Government Analyst, incidents where serious adverse effects or death have been reported, in case of banned drugs under Section 26 A, defects where in voluntarily the manufacturer withdraws drugs from the market etc.

3.0 Scope:

These guidelines is applicable to all quality defective product reports and to all reported incidents of safety and efficacy received for all drugs including vaccines & biological. These guidelines are expected to be followed by licensees (manufacturers, importers, stockists, distributors, retailers) and the recall could be voluntary or statutory. The procedure may also be used by drugs control authorities of central or state when urgent action is required to protect public or animal health. These guidelines would help in adopting to

stepwise procedures to be followed in recall strategy and also help in recall evaluation at every level and achieve compliance within the time frame.

4.0 Definitions:

Recall: Removal or correction of marketed products for the reasons relating to deficiencies in quality, safety or efficacy, including labeling considered to be in violation of the laws.

Batch Recall: Process for removal of selected batch/es of a product which are found to be defective and pose health risk to the consumers if left in the market.

Batch (Lot): A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits.

Customer: Any person, firm or party buying/receiving goods from the company for storage, distribution and sale.

Voluntary Recall: A recall initiated by the licensee (in case of loan licensee jointly the contract giver and contract acceptor) as a result of abnormal observation in any product quality during periodic review (Internal / External) or investigation of a market complaint or any other failures.

Statutory Recall: A recall directed by Drug Control Authorities after notifying that product is considered to be in violation of the laws. e.g., Declared as Not of Standard Quality by Government Analyst and Banned under 26A of Drugs and Cosmetics Act 1940 (as amended from time to time)and as well as contravention of Rule 104-A of Drugs & Cosmetics Rules1945(as amended from time to time)

5.0 Recall Classification:

Recall classification is a numerical designation, I, II, or III, that is assigned to a particular product recall that indicates the relative degree of health hazard by country regulatory authorities.

In case of not of standard quality drugs, the recommendations of 39th DCC guidelines for category A,B and C may be accordingly adopted for Class I, Class II and Class III until further recommendations if any. All banned drugs &products for which license is suspended, cancelled which are in circulation in market shall also be considered to be Class I recalls only.

Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death and as well as banned under 26A of Drugs and Cosmetics Act 1940.

Class II is situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III is a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences**.**

6.0 Recall Procedures:

Any batch of a product not meeting the defined quality standards has to be recalled from the market. Recall can be of two types; Voluntary Recall and Statutory Recall.

6.1 Voluntary Recall:

Voluntary recall can be triggered by any incident that affects the quality, safety and efficacy of the batch/product in question such as

1. If the batch or batches are found to be not complying with the regulatory specifications during the post marketing stability study
2. If the batch is found to be defective during investigation of market complaint.
3. During any failure investigation, if it is observed that the failure under investigation might have adverse quality impact on already released batch (e.g. possibility of contamination, mix-up, degradation etc).
4. If any unusual observation is noted during visual inspection of retention samples which indicate an impact on quality of the product after investigation.
5. If the post marketing surveillance reports /pharmacovigilance reports indicates that there is serious safety risk associated with the product.

6.2 Statutory Recall:

Statutory recall can be triggered in response to the direction or mandate by the Drug regulatory authorities (Central/State) in one or more of the situations as follows :

1. To recall the drug product/batch, considered to be in violation of the laws it administers such as not of standard quality etc.
2. To recall the banned drugs.
3. Labeling and / or Promotional materials, that are considered to be in violation of law.
4. Product, violation Rule 106 (Diseases under Schedule J)

7.0 Level of Recall:

The level (or depth) of recall of a product/batch shall be determined based on recall classification and level to which distribution has taken place.
There are three levels of recall such as consumer/user, retail and wholesale.

Consumer or User Level: which may vary with product, including any intermediate wholesale or retail level. Consumer or user may include individual consumers, patients, physicians and hospitals.

Retail Level:- recall to the level immediately preceding consumer or user level. It includes retail groceries, pharmacies, hospital pharmacies, dispensing physician, institutions such as clinics and nursing homes, etc.

Wholesale Level: all distribution levels between the manufacturer and retailer.

All Class I recalls shall be executed to the levels of Wholesale/Distributors, retail, and consumer. In such cases, public announcements shall be made using print/electronic media aids viz. Newspapers, Television, Radio etc.

All Class II recalls shall be executed up to the levels of wholesale and retail.

All Class III recalls shall be executed up to the levels of wholesale.

8.0 Time Lines for Effective Recall System & Rapid Alert:

Based on the category of risks involved, a time line of within 24 hours up to a maximum of 72 hours for Class I recall, for class II recall up to a maximum of 10 days and for Class III recall up to a maximum of 30 days is allowed.

The time line for initiation of recall procedure to commence from the receipt of information as notified by the concerned State/ Central Drugs Control Department under statutory recall or voluntary recall by the manufacturer on its own.

The recall has to be initiated immediately without any prejudice of the outcome of Section 25(3) and Section 25(4) of the Drugs & Cosmetics Act 1940 for adducing the evidence. The time line for stopping sale/distribution of defective product under Class I shall be ensured within 24 hours and the physical recall being completed within 72 hours. The Class II and Class III recalls shall be ensured upto 10 and upto 30 days respectively.

9.0 Procedure for Rapid Alert & Recall System:

As soon as the product/batch(es) to be recalled is/are identified, licensee or representative of licensee or QA in charge shall review the information related to the defective product/batch(es) and decide about recall as per the procedure established.

The decision on recall of the defective product/batch shall be made within 24hours up to maximum of 72 hours for Class I recall upon receipt of the intimation.

Within 24hours of the decision taken for the recall of the product/batch(es) the communication shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, fax, SMS etc to the entire supply chain.

The licensee/representative of licensee where the product is marketed shall inform the concerned regulatory authorities where the product batch(es) in question was distributed immediately after the decision of recall has been taken. Further actions on recall will be undertaken according to class of recall.

Recall classification of the product/batch in question shall be done based on the risk assessment in line with the recall classification as given in definition.

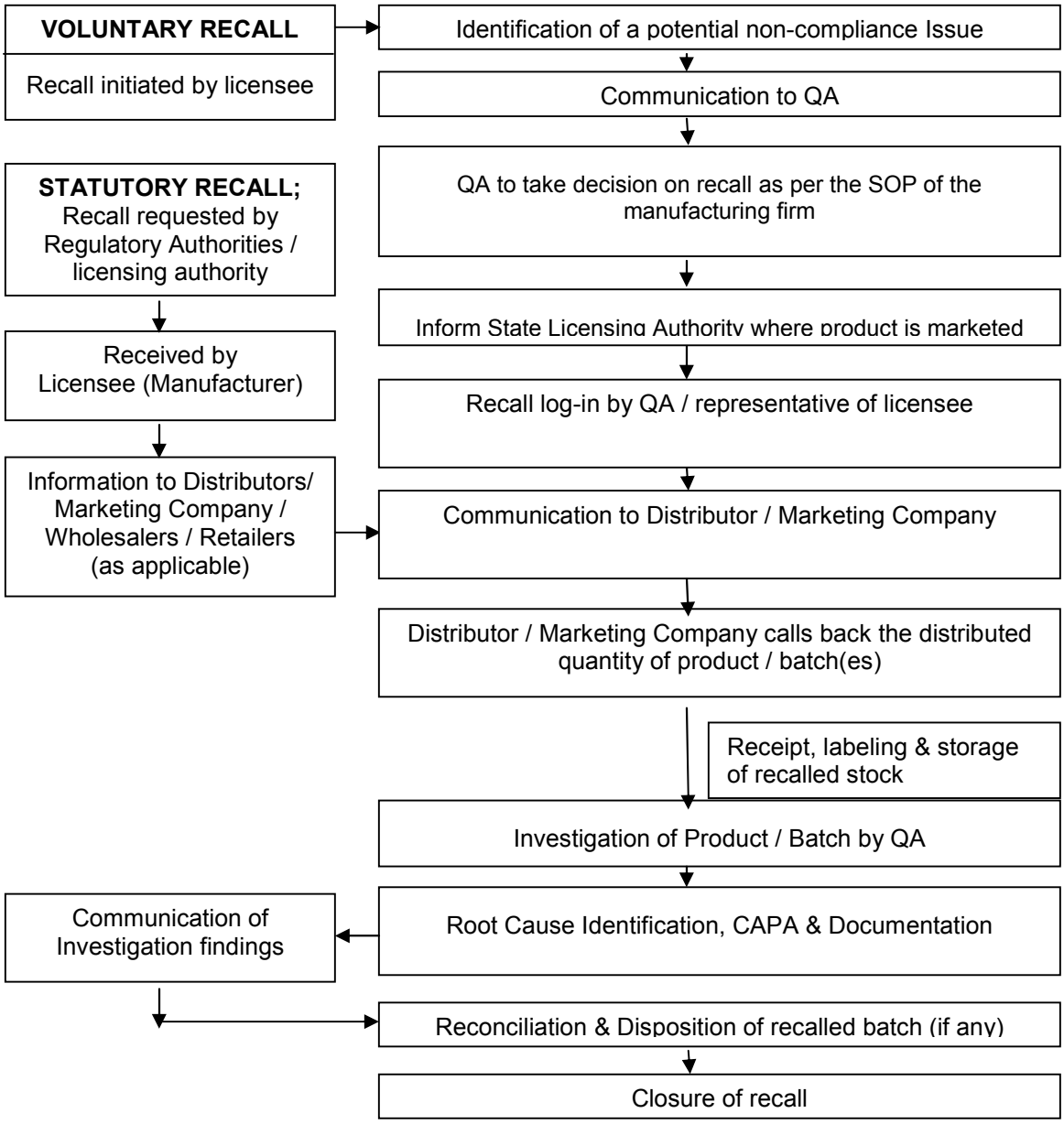
It shall be the responsibility of the manufacturer and marketing company to inform up to retail level on the reason of recall in his freeze stock notice.

It shall be the responsibility of distributor/marketing company/ retailer to inform the stock position of product being recalled to his immediate supplier or manufacturer and also his area Drugs Inspector.

The recall notice received, the stock at that time, the procedure for freezing the stock and returned back records shall be maintained by the distributor/retailer and shall be made available for verification by area Drugs Inspector who shall verify and report on its timely freezing and return.

10.0 Overview of Process Flow Rapid Alert & Recall System:

Activity



*** Note: Recall shall be initiated & completed as per timelines of recall classification.**

11.0 Stepwise Recall Procedure:

The licensee/representative of licensee/Quality Head in charge shall enter the details in the 'Recall Log' and assign a unique recall reference number representing the serial number for a particular year in which the recall has been initiated.

The licensee/representative of licensee/ Quality Head in charge shall inform the Distributor/Marketing Company with fastest mode of communication which may include email, telephone, fax, sms etc. to stop further distribution of the batch(es) in the stock and call back the stock available with the distributors, retailers etc, depending on the seriousness of the defect.

"Product/batch Recall Notice" shall be filled and sent by licensee/representative of licensee/ Quality Head in charge to Distributor / Marketing Company.

Distributor / Marketing Company shall immediately check the distribution record to identify the Customers and Warehouse, depots where the subject product / batches have been distributed and forward the copies of the Recall Notice to them for further necessary action.

The Head of depot(s) shall fill 'Recall Notification' and forward it to all distributors to return all unsold stock. Simultaneously, the heads of respective depots /ware houses shall block the available stock. The Distribution Head shall ensure the blockage of stock for further sale by reviewing the record.

The distributor(s) shall send the "Return Feedback" along with goods (if any) to the depots. All the returned stocks shall be further forwarded to the ware houses.

The Head of ware houses shall send a periodical report to licensee/representative of licensee /QA head of the stock available with them and the returns received from depots.

Head of ware house shall reconcile the stocks of the recalled materials against the total quantity of distributed material and fill the "Summary Report of Product / Batch Recall". The copy shall be forwarded to licensee/representative of licensee/QA in charge for review and necessary action.

The recall of the product/batch shall be completed depending on the class of recall within the stipulated time.

12.0 FOLLOW-UP ACTION OF RECALLED GOODS:

The follow-up action consists of a check on the effectiveness of the recall, an investigation of the reason for the recall and remedial action taken to prevent a recurrence of the defect.

The licensee/representative of licensee/QA Head shall monitor the recall process of product/batch to determine whether the recall is progressing satisfactorily.

The stocks of recalled goods shall be placed under "Quarantine" and stored separately under lock and key in a secure area until further decision.

Wherever required, QA Head of the manufacturing site shall perform the physical inspection of recalled goods and collect sample from recalled goods for investigation to establish the root cause of the product quality defect.

The investigation of the recalled batch(es) shall be conducted as per the SOP of the licensee, on "Investigation of Non-conformities" to identify the root cause of the failure and initiate corrective and preventive actions

Impact assessment shall be conducted on other batches of the concerned product and further extended to batch(es) of other product(s), wherever applicable.

If the cause of recall is established to be quality issue associated with any of the raw material used, then the traceability of that material shall be established in all the product/batches.

Alternatively execute the transaction through records to identify the batches / products in which the identified material has been used.

Monitoring the relevant data i.e. Material, Plant and Batch Number in respective fields.

Identify the raw material traceability in different formulations and its functions.

List all raw materials along with batch numbers and the respective quantities used in those batches.

List all the products along with batch numbers and the respective quantities used in those batches.

Calculate the total quantity by adding individual quantities used in various products / batches.

Monitoring of the material movement to get the complete overview of stock for that particular material in the plant and extract the information about total quantity received and the balance quantity.

The balance stock, if any shall be verified against the actual physical stock available. QA shall block the remaining available stock.

All material shall be accounted for after the reconciliation

The decision to recall, if necessary, any of the impacted batches shall be made after product quality assessment.

Based on conclusion of the investigation findings, the QA Head / representative of licensee shall direct the Distributor / Marketing Company for appropriate disposition of the batch(es) of the recalled goods as per the regulations.

13.0 MOCK RECALL:

Mock recall shall be carried out for at least one batch of any product, dispatched for sale where maximum distributors are involved, to test the effectiveness of the arrangements of recall. Effectiveness of recall procedure can also be checked by 'evaluation of a real recall'.

During mock recall traceability shall be performed for at least, one of the raw material used in the batches identified for mock recall.

Mock Recall shall be performed at least once for the longest distribution chain and whenever there is a change in distributor/marketing company.

Records of such mock recall should be maintained by the QA Head of the company.

Abbreviations:

Acronym	Full Form
QA	Quality Assurance
CAPA	Corrective and Preventive Action

References:

1. The Drugs & Cosmetics Act 1940 & Rules 1945.
2. The WHO TRS for GMP Guidelines.
3. Work Shop on Recall & Rapid Alert System, held at New Delhi Office from 27th to 30th August 2012 organized by CDSCO in collaboration with WHO.
4. USFDA documents on recall.
5. The Guidelines on Recall & Rapid Alert System for Drugs including Biologicals and Vaccines.
6. 39th DCC Guidelines.

	TITLE	SOP No.	
	Standard Operating Procedure for regulators (State/Central Drugs Control Departments) Recall and Rapid Alert System for Drugs including Biological & Vaccines	Effective Date	
		Review Date	
		Supersedes	
Division Name		Revision No.	00
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Prepared By		Checked By		Approved By		Authorized By	
Name		Name		Name		Name	
Designation		Designation		Designation		Designation	
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

1.0 Purpose

To lay down uniform procedure and execute the statutory powers as per Drugs & Cosmetics Act and Rules for directing and ensuring rapid alert & effective recall/destruction of drug products from the market, which are found not of standard quality and / reported of any serious adverse effects/death.

2.0 Scope:

This document is applicable to all /licensing authority for manufacture, stock, distribution or sale and for harmonized implementation within the state as well as for interstate co-ordination.

3.0 Responsibility:

3.1 The SLA/CLAA (incase of CLAA approved products) shall be responsible for issuing letter / order for stop use at all levels and recall of products which are found not of standard quality to licensee.

3.2 The SLA shall be monitoring and ensuring the action taken by the licensee at all levels as per his instructions

3.3 The licensee is responsible for recall of product at all levels from supply chain and shall also be responsible according to the provisions for product recalls and also for the complaint and adverse reactions as envisaged in Para 27 and Para 28 of Schedule M and Rule 74(j) & 78(i) of the Drugs & Cosmetics Rules.

3.4 For interstate co-ordination & communication, the zonal offices of CDSCO of their respective jurisdiction are responsible.

4.0 Procedure:

4.1 As soon as the drug is declared as not of standard quality in Form 13 – (Certificate of Test/Analysis) by Government Analyst and same is forwarded to the concerned Drugs Inspector by the laboratory. On the receipt of said report, the concerned inspector shall

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Designation		Designation		Designation		Designation	
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

immediately intimate to their CA (when the manufacturer is not located in their state) & concerned LA (when manufacturers is located in their state).

4.2 The CA of that state under whose jurisdiction the sample is drawn shall inform to the concerned CA/SLA under whose jurisdiction manufacturer is located and also to the zonal offices of CDSCO for co-ordination.

4.3 The SLA under whose jurisdiction manufacturer is located shall direct the manufacturer to stop further sale or distribution and recall of batch of the product by means of sending the recall notice i.e. " Order to stop sale or distribution or use of drug & recall notice (Annexure I) to the manufacturer (if located in his jurisdiction) and licensee shall recall such products (Annexure II) as per the recall classification (Refer - Guidelines for Recall & Rapid Alert System) & record the details in Recall log.

4.4 The SLA shall communicate to stop the usage of the drug immediately in case of Class-I recall as per the Guidelines for Recall & Rapid Alert System through fastest mode of communication such as by mass media through news papers, TV and in the departmental web portal.

4. 5 The SLA/CA shall direct the area Drugs Inspector to freeze the stock in case of Class I recall for that batch if available for sale or distribution and the Drugs Inspector shall report action to SLA/CA the action taken within the stipulated time line.

4.6 The Manufacturer shall be responsible for communication of recall at appropriate levels in the supply chain with the status on the stock in position and the progress of recall through Recall Notice to distributors / Marketing company / stockiest / retailers (Annexure – III) & summary report of recall (Annexure - IV).

4.7 Recall status shall be intimated by the licensee at manufacturer/whole sale/retail level to the area Drugs Inspector who shall be responsible for assessing the effectiveness of recall and shall intimate the same to the SLA.

4.8 The Manufacturer shall intimate to the concerned LA after completion of recall within the stipulated time line. The LA shall intimate the update to concern SLAs / CAs and CAs of respective CDSCO Zone/Sub-zone (in the matter where communications to interstate SLAs is required)

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Prepared By		Checked By		Approved By		Authorized By	
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Date		Date		Date		Date	

4.9 The SLA may initiate for investigation on not of standard quality drugs not only for the impugned batch but also if other batches could also be affected.

5.0 After completion of investigation such products may be destroyed in presence of the area Drugs Inspector as instructed by SLA as per Bio Medical Waste Management & Handling Rules, 1998 and records shall be maintained.

5.0 Annexure / Format

Annexure/Format No.	Title
Annexure - I	Order to stop sale or distribution or use of drug & recall notice.
Annexure - II	Recall log.
Annexure - III	Recall notice to distributors / marketing company / stockists / retailers.
Annexure - IV	Summary Report of Recall

6.0 Abbreviation

Acronym	Full Form
SOP	Standard Operating Procedure
QA	Quality Assurance
SLA	State licensing Authority
CLAA	Central License Approving Authority
LA	Licensing Authority
CA	Controlling Authority
CDSCO	Central Drugs Standard Control Organization
NSQ	Not of Standard Quality
WH	Ware House

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Designation		Designation		Designation		Designation	
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

7.0 References

Doc. No.	Title
1	The Drugs & Cosmetics Act 1940 & Rules 1945.
2	Good Distribution Practices by WHO.
3	Good Manufacturing Practices by WHO.
4	The Guidelines on Recall & Rapid Alert System for Drugs including Biologicals and Vaccines
5	The Bio Medical Management & Handling Rules, 1998.
6	39th DCC Guidelines

ANNEXURE – I

ORDER TO STOP SALE OR DISTRIBUTION OR USE OF DRUG & RECALL NOTICE

FILE NO.: ……

TO, **DATE:** …….

< Name and Address of the Licensee >

This is to intimate you that < *Name of the Product*----------, *Batch No.* ---------, *Date of Manufacture*----------, *Date of Expiry*----------, *Manufactured By M/s (Name of the Manufacturer and address*----------*)*> has been declared by < *Name of the Laboratory*----------> as not of standard quality; vide < *Letter/Report Number …….. dated …….. >* for the reasons that <*reasons to declare the product as NSQ*----------> declared as NSQ whose copy is enclosed for your reference. The above drug has reported to be causing serious adverse events /death.

You are, therefore, directed to stop distribution, sale or use of above mentioned drug and to initiate its recall from the market. Also you are directed to submit details within ---------- hours/days as per recall class ----------to this office as per the enclosed formats.

(Signature, Name and Address of CA/SLA)

Copy for information and necessary action to:

1. The State Licensing Authority of all the States/UTs of Union of India for action to stop distribution, sale or use of above mentioned drug in their jurisdiction.
2. The Zonal or Sub-Zonal Office of concerned CDSCO.

ANNEXURE - II

RECALL LOG
(to be filled in by licensee / representative of licensee)

Recall ref. no.	Time & Date of recall Initiation	Product name	Batch ./ Lot No	Mfg Date	Exp Date	Reason for recall	Classification [Class I,II,III]	Quantity Produced / B. Size (A)	Unsold or Undistributed quantity in possession (B)	Quantity Distributed (C)	Quantity Returned / Recalled	Closure Date & Sign.	Remarks

ANNEXURE – III
RECALL NOTICE TO DISTRIBUTORS / MARKETING COMPANY / STOCKISTS / RETAILERS

Part A: (To be filled by licensee / representative of licensee)

To;	…… ……	Recall Ref.No.: …… Date:……...

Please stop further distribution/sale of below mentioned product/batches with immediate effect. Kindly recall the stocks of these batch/es from the market. All unsold goods in the warehouse and recalled goods to be quarantined till further advice.

Product Details (Name/Strength/Dosage/Pack)	**Batch/ Lot no.**	**Mfg. date**	**Expiry date**	**Batch Size**	**Quantity released for sale**

Type of recall: (Tick as appropriate) Statutory/ Voluntary

Recall classification: Class I Class II Class III

Extent of recall : WH Depot Distributors Retailers Authorized Exporter (in case of exports)

Hospitals/Healthcare Professionals/Consumers Agents in importing countries

Reason for recall:

Licensee / representative of licensee
(Name, Sign & date)

Manufacturing site: ……. Mfg.Lic.No.: ……...

ANNEXURE – IV

SUMMARY REPORT OF RECALL

Part A: To be filled by Distributor / Retailer as applicable

Recall Ref. No.		**Date:**		
Product name				
Batch no.				**Mfg Date:**
Reason for Recall				
Name of Customer	**Qty. Received on purchase invoice (A)**	**Quantity Sold (B)**	**Quantity Un distributed / Stock in Hand (C)=(A)-(B)**	**Quantity Received from Customer in response to recall(B)**
Total Quantity	**(G)=**	(H)	(E)	(F)
Stock not distributed (E)				
Quantity available in Warehouse after Recall (E+F)				
Total quantity received with purchase invoice (Purchase Invoice No., Date, etc.)(G)				
Justification for any Deviations observed During reconciliation				
Stock / Sale License No.				
Prepared by: Retailer / Wholesaler (Personnel Sign/Date)				

Part B: To be filled by manufacturer

Batch Disposition:	Quantity:…….. to be; Batch Size: Destroyed Reprocessed Reworked Any other (specify)

Recall Summary: (Also mention, action taken if product was still available for sale or use) Licensee / Representative of licensee

STANDARD OPERATING PROCEDURE FOR MANUFACTURERS ON RECALL & RAPID ALERT SYSTEM FOR DRUGS INCLUDING BIOLOGICALS & VACCINES

1.0 Purpose:

To describe a procedure defining an action plan for recall/removal of product from use or supply, or subject to corrective action, for reasons relating to their quality, safety or efficacy.

2.0 Scope:

This document is applicable to all licensees engaged in manufacture for stock, distribute, sale of drugs including Vaccines & Biologicals.

3.0 Responsibility:

3.1 Director or management of the manufacturing firm

- To monitor and ensure effective recall.

3.2 Quality Head of the manufacturing firm will be responsible for:

- Informing the management about any product defect which may require recall.
- Information to regulatory authorities immediately after recall decision is taken
- Issuance of recall notice to all distributor/ marketing company.
- Overseeing the system for receiving, verification, quarantining, segregation and securing of recalled stock.
- Labelling of the recalled stock.
- Investigation of the incident which resulted in product recall.
- Making decision on disposition of recalled stock as per SOP of the firm.

3.3 Warehouse Head will be responsible for:

- Receipt, verification, quarantine/ segregation and secured storage of recalled stock.
- Informing QA about the recalled goods.
- Providing support during recall investigation

3.4 Distributor/ Marketing Company for:

- To ensure the removal of impugned batch of product from the market in a stipulated time as per class of the recall.

- To Co-ordinate with Wholesalers / retailers for the recall of batch(es) in the market.

4.0 PRODUCT RECALL PROCEDURE:

4.1 Any batch of a product not meeting the defined quality standards has to be recalled from the market.

4.2 As soon as the product/ batch(es) to be recalled is /are identified, Head of Quality shall review the information related to the defective product/ batch/es received and decide about recall in consultation with management of the company or as per SOP of the company.

4.3 The decision on recall of the defective product/batch shall be made within the timeline given in the guidance document of CDSCO.

4.4 After the decision taken for the recall of the product/ batch(es),the communication shall be sent stating the severity of the defect, using the fastest mode of communication which may include email, telephone, fax, SMS etc.

4.5 Representative of Licensee of manufacturing firm shall inform the concerned regulatory authorities where the product batch(es) in question was distributed, immediately after the decision of recall has been taken. Further actions on recall will be undertaken as directed by the regulatory authority.

4.6 Recall classification of the product/batch in question shall be done based on the risk assessment in line with the recall classification as given in the guidance document for recall and rapid alert system.

5.0 STEPWISE EXECUTION OF RECALL

5.1 Quality Head shall enter the details in the “Recall log’, and assign a unique recall reference number representing the serial number for a particular year in which the recall has been initiated. (Annexure II)

5.2 Quality Head of respective manufacturing sites (including contract manufacturing sites) shall inform the Distributor and the Marketing Company with fastest mode of communication which may include email, telephone, fax, SMS etc. to stop further distribution of the batch/es in the stock and call back the stock available with the distributors, retailers etc. depending on the seriousness of the defect.

5.3 "Recall notice to distributors/Marketing Company/Stockiest/Retailers" (Annexure III) shall be filled and sent by respective manufacturing sites' Quality Head to Distributor/ Marketing Company.

5.4 Distributor/ Marketing Company shall immediately check the distribution record to identify the customers (wholesaler/retailer), depots where the subject product/batches have been distributed and forward the copies of the Recall Notice to them for further necessary action.

5.5 The Head of depots shall fill "Recall Notice to distributors/Marketing Company/Stockists/Retailers' (Annexure III) and forward it to all further distributors if any to return all unsold stock. Simultaneously, the heads of respective depots/ wholesale/ retail shall Block the available stock. The Distributor/ Marketing Company shall ensure the blockage of stock for further sale by reviewing the record.

5.6 The distributors/ Marketing Company shall send the "Summary Report of Recall" as per the specimen given in (Annexure IV Part A) along with goods (if any) to the depots. All the returned stock shall be further forwarded to the warehouse.

5.7 The Head of warehouse shall send a periodical report to Quality Head of respective manufacturing site, of the stock available with them and the returns received from depots.

5.8 Warehouse Head shall reconcile the stock of the recalled material against the total quantity of distributed material and fill the "Summary report of Recall" (Annexure IV, Part A). The copy shall be forwarded to Quality Head for review and necessary action (Annexure 4, Part B); the copies of which shall be sent to the Distributor/ Marketing Company/ Marketing Head and wherever applicable.

5.9 The recall of the product/batch shall be completed within the timeline given in the guidance document.

6.0 FOLLOW-UP ACTION ON RECALLED GOODS

6.1 The follow-up action consists of a check on the effectiveness of the recall, an investigation of the reason for the recall and remedial action taken to prevent a recurrence of the defect.

6.2 Quality Head of the respective manufacturing site shall monitor the recall process of product/batch to determine whether the recall is progressive satisfactorily.

6.3 The stocks of recalled goods shall be placed under "Quarantine" and stored separately under lock and key in a secure area until further decision.

6.4 Wherever required, Quality Head of manufacturing site shall perform the physical inspection of recalled goods and collect sample from recalled goods for investigation to establish the root cause of the product quality defect.

6.5 The investigation of the recalled batch/es shall be conducted as per the SOP, on "Investigation of Non-conformities" to identify the root cause of the failure and initiate corrective and preventive actions.

6.6 Impact assessment shall be conducted on other batches of the concerned product and further extended to batch/es of other product/s , wherever applicable.

6.7 If the cause of recall is established to be quality issue associated with any of the raw material used, then the traceability of that material shall be established in all the product/s batches where it has been used

6.8 Alternatively execute the transaction through records to identify the batches / products in which the identified material has been used

6.9 Monitoring the relevant data i.e, Material, Plant and Batch Number in respective fields.

6.10 Identify the raw materials traceability in different formulations and its distribution.

6.11 List all the raw materials along with batch numbers and the respective quantities used in those batches.

6.12 Calculate the total quantity by adding individual quantities used in various products/ batches.

6.13 Monitoring of the material movement to get the complete overview of stock for that particular material in the plant and extract the information about total quantity received and the balance quantity.

6.14 The balance stock, if any in the record shall be verified against the actual physical stock available. QA shall block the remaining available stock.

6.15 All the material shall be accounted for after the reconciliation.

6.16 The decision to recall, if necessary, any of the impacted batches shall be made after product quality assessment.

6.17 Based on conclusion of the investigation findings, QA Head shall direct the Distributor/ Marketing Company and respective business Head for appropriate disposition of the batch/es of the recalled goods as per the regulations.

7.0 Mock Recall Procedure

7.1 Mock recall shall be carried out for at least one batch of any product, dispatched for sale where maximum distributors are involved, to test the effectiveness of the arrangements of recall. Effectiveness of recall procedure can also be checked by 'evaluation of a real recall'.

7.2 During mock recall traceability shall be performed for at least, one of the raw material used in the batches identified for mock recall.

7.3 Mock Recall shall be performed at least once for the longest distribution chain and whenever there is a change in distributor/marketing company.

Annexure / Format

Annexure/Format No.	Title
Annexure - II	Recall log.
Annexure - III	Recall notice to distributors / marketing company / stockists / retailers.
Annexure - IV	Summary Report of Recall

Abbreviation

Acronym	Full Form
SOP	Standard Operating Procedure
QA	Quality Assurance
SLA	State licensing Authority
CA	Controlling Authority
CDSCO	Central Drugs Standard Control Organization
NSQ	Not of Standard Quality
WH	Ware House