National Agency for Food & Drug Administration & Control (NAFDAC)

Post Marketing Surveillance (PMS) Directorate

NAFDAC Guidelines for the Recall of Defective Medical Products

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1.0. General

1.1. These guidelines describe the responsibilities and expectations of individuals intending to participate in the recall of defective medical products suspected of being potentially harmful to consumers due to its defective quality, safety, or efficacy. For such a defective medical product, a recall shall be issued, and it must be removed from the market.

This is in line with ICH Q7 (15.14) (Good Manufacturing Practice) which emphasizes the importance of maintaining a robust system for managing recalls to ensure defective products are removed from the market efficiently and effectively.

This guidance document summarizes the series of activities to be undertaken in the event of a necessary recall to carry out recall operations effectively and efficiently.

1.2. This guidance document

1.2.1. prescribes the minimum requirements to ensure the quality and safety of the data generated and submitted to NAFDAC.

1.2.2. the classification of recalls, recall notification requirements, specific roles for different stakeholders in the recall process, and the basic requirements expected by NAFDAC concerning recall in line with ICH Q7 (15.4) (Good Manufacturing Practice).

1.2.3. also prescribes the minimum timelines necessary for initiating and conducting a recall of medical products in line with ICH Q10 (Pharmaceutical Quality System) which supports the need for clear guidelines and timelines to ensure the quality, safety, and traceability of products during a recall.

1.3. These guidelines should be followed to comply with timelines as issued by the agency.

It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold, or distributed in Nigeria unless it has been registered under the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guideline.

Ensure that the recall guidelines include a clear process for ongoing monitoring of the recall process throughout its duration. This will help identify potential issues early in line with ICH Q7 (Good Manufacturing Practice).

Note: *These Guidelines should be read in conjunction with all relevant IMDRF guidance documents.*

All Holders of Certificate of Authorization medical devices in the country are required to keep distribution records of where the devices have been supplied, including distributor centers and hospitals to:

(i) expedite any recalls of the medical devices
(ii) identification of manufacturers of each batch of devices

1.4. GLOSSARY Acronyms

ADR	Adverse Drug Reaction.
BMR	Batch Manufacturing Record
BPR	Batch Processing Record
NAFDAC	National Agency for Food and Drug Administration and Control
NRA	National Regulatory Authority
WHO	World Health Organization

2.0. Definitions of terms

Authentication: means self-checking of distribution history while accepting a shipment of medical products by the recipient (e.g., distributor, warehouse, hospital, institution, or retailer) as is required to verify the distribution history.

Authorization: means the permission granted by NAFDAC to any legal person or owner(s) of a company or firm to conduct manufacturing, import, export, sale, or supply of medical products under the NAFDAC Act Cap N1 LFN 2004.

Batch (or Lot): means a defined quantity of starting material, packaging material, or finished product processed in a single process or series of processes so that it could be expected to be homogeneous in the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity, and to complete certain stages of manufacture it may sometimes be necessary to divide a batch into some sub batches, which are later brought together to form a final homogeneous batch;

Batch No. (or Lot number): means a distinctive combination of numbers and or letters that specifically identifies a batch on the labels, the batch records, and the certificates of analysis, and that permit the production history of the batch to be traced and reviewed.

Batch Records Batch Manufacturing Record (BMR)/ Batch Processing Record (BPR) batch records: mean all documents associated with the manufacture of a batch of bulk product or finished product showing a history of each batch of product and all circumstances pertinent to the quality of the final products.

Consignee: Anyone who received, purchased, or possesses the medical product being recalled.

Consumer/Users: one who purchases medical products for its use. A Consumer/user may include individual consumers, patients, physicians, hospitals, etc.

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

Clinical investigational institutions: Institutions conducting clinical trials or clinical studies.

Defective Product Attributes: of a medical product that may affect the product's quality, safety and/or efficacy.

Distributor / Wholesaler means a person/entity, buying the medical products to sell again.

Distribution / Wholesale means sale to a person/entity, buying the products to sell again

General sales outlets: Include shops, supermarkets, and other vendors of general sales of medical devices and health technologies such as cotton wool, bandages, BP machines, etc. Also, found in Research institutions, Academic or scientific research institutions, Donated Medicines not registered in Nigeria, and health technologies applied in clinical trials and other clinical studies.

Health risk: Reasonable probability that the use of or exposure to a product may cause serious adverse health consequences or death; use of or exposure to the product may cause temporary or medically reversible adverse health consequences; or the outcome where the probability of serious adverse health consequences is remote.

Health technology: This is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve the quality of life (WHO).

Medicines distribution outlets: This, includes hospital pharmacies, clinics, and medical centers.

Manufacture: means all operations of production, quality control, release, storage, and related controls.

Manufacturer: means a company that carries out at least one step of manufacture.

Marketing Authorization: means a document issued by the NAFDAC under the NAFDAC Cap N1 LFN 2004, as a certificate of registration/enlistment of a medical.

Medical Product: means any drug intended for human use or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form.

Medical: Includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Agency (Medical may hereinafter be referred to as the product.)

Market Authorization Holder An agency/company which has been granted marketing authorization for medical product (s) and health technologies in Nigeria. The company is responsible for all aspects of quality, safety, efficacy/effectiveness, and compliance with conditions of registration.

Medical Product: For these guidelines; medical products include medicinal products and medical devices.

NOTE: These Guidelines should be read in conjunction with all relevant IMDRF guidance documents

Parallel importation: This means the importation into Nigeria by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical representative.

Parallel importer: A person licensed to carry out the business of parallel importation.

Product quality defect: An attribute of a medical product and health technology or its component that may affect the product's quality, safety, and efficacy, which is not in line with the approved product authorization or other marketing authorization.

Qualified person: A person designated as responsible for recalls by the MAH

Direct Lifting: Recalled products are taken off the shelf by the MAH or persons responsible for recall collect them directly from the premises where the product is stored or kept.

Quality Control Laboratory (QCL): means any laboratory notified for the test/analysis of medical products.

Recall: means the removal of specific batch/batches of a medical/product from the market for reasons relating to quality, safety, or efficacy and/or if they are not in line with the particulars provided in the registration/enlistment application of the product.

Recall classification: Recall Classification is the numerical designation, i.e., I, II, or III, assigned to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

Recall strategy: Recall strategy is a planned specific course of action to be taken in conducting a recall, which addresses the depth, need for public awareness, and extent of effective checks/follow-up for the recall.

Reference Regulatory Authority: means a regulatory authority as notified by any competent forum, board, or committee of NAFDAC for reliance.

Retail Sale means a sale other than distribution/wholesale.

Statutory recall A recall directed by NAFDAC upon notification of deficiencies in the quality, safety, and efficacy of a medical product and health technologies.

Statutory Recall: A recall directed by the Drug Regulatory Authority of Nigeria (NAFDAC) after notifying that the product violates the laws, the NAFDAC Cap N1, LFN 2004, The Drugs Act, 1976 and the rules framed thereunder.

Statutory withdrawal: A withdrawal directed by NAFDAC upon notification of deficiencies in the quality, safety, and efficacy of a medical product and health technologies.

Voluntary recall: A recall initiated by the manufacturer, market authorization holder, or agent because of abnormal observation in any product quality, safety, and efficacy during periodic review or investigation of a market complaint or any other failures.

Voluntary withdrawal: A withdrawal initiated by the market authorization holder or the agent because of abnormal observation in any product quality, safety, and efficacy during periodic review or investigation of a market complaint or any other failures.

Withdrawal The total removal of medical products and health technologies from the market for reasons relating to deficiencies in the quality, safety, and efficacy leading to cessation of its market authorization.

Wholesaler: An entity licensed by PCN to carry out the business of a wholesale dealer, procurement agency, and Central procurement agencies of medical products and health technologies.

3.0. Recall Procedure

3.1. The purpose of a recall is to safeguard patients and consumers from potential harm caused by using a defective medical product. A defective medical product is suspected to be harmful under normal conditions of use, that does not comply with its marketing authorization (its registered) specification that is lacking in medical efficacy or that has not been manufactured under accepted standards of Good Manufacturing Practices (GMP). Refer to ICH Q7 (Good Manufacturing Practice) which underlines the importance of having an effective recall procedure to promptly remove defective products from the market and protect public health.

3.2. The Marketing Authorization Holder (MAH) is primarily responsible for implementing a full recall, whether voluntary or statutory. The document also includes a sample recall letter to be issued by the MAH to its distributors, marketing firms, retail outlets, etc., provided in Annexure-III. Recall may be because manufacturers, wholesalers, and retailers carry out their legal and moral responsibility to protect the public health from the products that represent a risk of health hazard, injury, or are otherwise defective.

Note: All importers of supplied medical devices in the country are required to keep Distribution records of where the devices have been supplied, including distribution centers and hospitals, to:

(i) expedite any recalls of the medical devices,

(ii) identify the manufacturers of each batch of devices.

3.3. In almost all cases, a product recall can be divided into the following five stages:-

i. Receipt of Information of Defective Product (Problem Report)
ii. Submission of Information for Assessment of a Recall
iii. Assessment of Recall
iv. Recall communication to remove defective products from the market
v. Monitoring and Evaluation of Recall

3.4. Include a flowchart or checklist within the guidelines to outline each step of the recall process, ensuring that all team members understand their responsibilities and timelines in line with ICH Q10 (Pharmaceutical Quality System).

4.0. Receipt of Information of Defective Product (Problem Report)

A recall might be initiated voluntarily by the MAH of a product because of complaints or reports related to the quality, safety, or efficacy of a defective medical product. In this case, the MAH shall inform NAFDAC regarding the details of the recall including the type of problem identified in the product, source of complaint, details of the product (Brand name, Generic name, Strength, Pack size, Batch No., Mfg. Date, Exp. Date, Batch size and list of distributors), and action initiated so far. All the stated information shall be

provided keeping in view the timelines and procedures explained further in these guidelines in line with ICH Q10 (Pharmaceutical Quality System) which supports the need for thorough documentation and communication and ICH Q7 (6.1-6.18) (Good Manufacturing Practice) which emphasizes that complete and accurate documentation is crucial for ensuring product quality, facilitating regulatory compliance, and supporting the traceability of products throughout their lifecycle. The MAH shall send information to NAFDAC before they decide on recall. When the need for recall has been established an appropriate recall strategy may be devised. Alternatively, NAFDAC can also order a statutory recall of a product to the MAH upon receipt of a defective product report.

The reports or complaints leading to a statutory recall shall be generated by the following means:

i. Healthcare professionals, physicians, pharmacists, dentists, and patients.
ii. Test/analysis report of products by NAFDAC Quality Control Laboratories.
iii. Recall of products by principal manufacturer abroad or by the overseas National Regulatory Authorities or from information received directly from other NRAs or WHO.
iv. Hospitals or Research institutes.
v. Manufacturers, or distributors, or wholesalers, or pharmacies, or drug sale outlets (retailers).

Upon receipt of information from NAFDAC, the MAH shall analyze the information and immediately initiate the recall of the product in question following the procedure provided in these guidelines.

4.1. The Director, PMS on Risk Assessment and Recall of SF Products

The Responsibilities of the Director, PMS are given as.

a. Receiving and assessing reports of suspected defective medical products.
b. Determination of class of recall, and level of recall, and devise a strategy for effective recall.
c. Advising and monitoring necessary actions by the relevant licensee.
d. Communicating the details of actions to be executed by the relevant stakeholders.
e. Recommendations to the DG on appropriate action.
f. Monitor the effectiveness of recall and recommend follow-up actions.

This aligns with ICH Q9 (Quality Risk Management) in assessing risks associated with defective products and ensuring that recalls are conducted effectively.

4.1.1. The Director, PMS will achieve these goals and classify the risk by assessing the health hazard associated with the type of defect. For the said purpose, the following parameters can be taken into consideration:

i. Whether any disease or injuries have already occurred from using the product.
ii. Whether existing conditions could contribute to a clinical situation that exposes humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and, or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
iii. Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals at greatest risk.
iv. Assessment of the seriousness of the health hazard to which the at-risk populations would be exposed.
v. Assessment of the likelihood of occurrence of the hazard.
vi. Assess the immediate or long-term consequences of the hazard based on these factors. The Director, PMS will determine the recall classification to indicate the relative degree of the health hazard of the product being recalled or considered for recall and propose a recall strategy. Refer to ICH Q9 (Quality Risk Management) which provides a framework for systematically assessing and classifying risks.

4.2. Submission of Information for Assessment of a Recall

4.2.1 When an MAH initiates the recall of a product, **they shall notify NAFDAC about the recall situation, and all relevant information required for the assessment of the recall on the Recall Assessment Form (Annexure-I).** The information provided in Annexure-I shall be completed in all aspects and providing defined timelines, appropriately signed and stamped by a person nominated as the focal person for recalls by the MAH in compliance with ICH Q7 (Good Manufacturing Practice). The information required for assessment of the recall generally includes the following three categories.

a. Details of the Problem
    i. Name and contact of the person reporting the problem.
    ii. Date of problem reported.
    iii. Problem location.
    iv. Problem nature or type of defects in the product.
    v. Any similar problem reports.
    vi. Results of quality control tests and other investigations on suspected or other samples.
b. Details of the Product(s) (Refer to ICH Q10 (Pharmaceutical Quality System) which supports the need for a comprehensive product detail

to ensure that all aspects of the recall are managed effectively and that the impact on the market is minimized).

i. Proprietary (brand) name of the product, dosage form, strength, and active ingredients
ii. Registration/enlistment number and pack size details.
iii. Batch number(s), quantity, manufacturing and expiry date.
iv. Manufacturer/importer name with contact details and local distribution list.
v. If the product was exported, then also provide details of importing country(ies).

c. Risk Assessment and Proposed Action by Licensee (Refer to ICH Q9 (Quality Risk Management) which provides guidance on conducting risk assessments).

i. Assessment and evaluation of potential hazards to consumers.
ii. Proposed action.
iii. Proposed recall classification and level; and
iv. Availability of alternative products.

4.3. Assessment of Recall

The MAH shall submit an initial report to NAFDAC following the timelines provided in this document. The Director, PMS on risk assessment and recall of SF products will assess the information provided by the firm and information provided by the QCL (in case of a statutory recall) and will finalize the Class of recall and level of recall and devise a strategy for the recall process. This information will then be shared with the MAH in line with ICH Q10 (Pharmaceutical Quality System) which emphasizes the importance of collaboration between regulatory authorities and the MAH to ensure the effective implementation of the recall strategy. Provided below are the details of the classification of recall, level of recall, and the recall strategy.

Implement regular training sessions for the MAH and NAFDAC staff on how to conduct risk assessments effectively, using case studies to illustrate best practices in line with ICH Q9 (Quality Risk Management).

4.3.1. Recall Classification

Recall classification is a numerical designation, I, II, or III assigned to a particular recall. ICH Q9 (Quality Risk Management) supports the classification of recalls based on the level of risk posed by the product defect, ensuring that the response is proportionate to the potential health hazard.

This classification indicates the relative degree of health hazard presented by the product being recalled and determined by regulatory authority(ies). Details of these classes are given below.

Class	Risk Classification	Examples
Class I	The defect presents a risk of death or disability.	Wrong product (label and contents are different products) • Correct product but wrong strength, with serious medical consequences. • Microbial contamination/any foreign particle visible with the naked eye in a sterile injectable of sterile injectable or ophthalmic product. • Chemical contamination with serious medical consequences. • Mix up of products (‘rogues ‘) within a pack. For example, two different blister strips within one outer carton, or two different tablets within the one blister strip. • Wrong active ingredient in a multi-component product with serious medical consequences. • Serious adverse reactions that are batch or product related. • Any other situation that the Competent Authority or the committee may consider.
Class II	The defect may cause mistreatment or harm to the patient and may cause **temporary or medically reversible** adverse health consequences, that are not life-threatening.	• Mis-labelling - wrong or missing text or figures. • Missing or incorrect information - leaflets or inserts. • Microbial contamination of non-injectable, non-ophthalmic sterile products with medical consequences. • Chemical/physical contamination (significant impurities, cross-contamination, particulates). • Mix up of products. For example, a case of product A contains one or more packs of product B. • Non-compliance with specification (e.g. assay, dissolution, stability, content uniformity, fill/weight). • Insecure closure with serious medical consequences (e.g. cytotoxic, child-resistant containers, potent product).

		• Any other situation that the Competent Authority or the Committee may consider.
Class III	The defect is **unlikely to cause harm to the patient**, and the recall is carried out for other reasons, such as non-compliance with the marketing authorization or specification.	• Faulty packaging - for example, wrong or missing batch number or expiry date. • Any other situation that the Competent Authority or the Committee may consider.
Class IV	These are known as "Medical product notifications" and in these scenarios, NAFDAC issues "Caution in Use" notices, where there is no threat to patients or no serious defect likely to impair product use or efficacy.	These are generally used for minor defects in packaging or other printed materials. "Caution in Use" notices may also be issued where a defect has been identified but due to supply concerns product cannot be recalled, in these instances, the alert will be used to provide advice to healthcare professionals.

- Introduce periodic reviews of recall classifications to assess whether the classifications are being applied consistently and correctly across different cases in line with ICH Q9 (Quality Risk Management).

4.3.2. **Levels of Recall / Depth of Recall**

The level (or depth) of recall of a product/batch shall be determined based on the level to which distribution of the product in question has taken place. The levels of recall are given as under:

Level of recall	**Details**
Consumer / User level	Consumer or user level may include individual consumers, patients, physicians, and hospitals
Retail level	Recall to the level immediately preceding the consumer or user level. It includes retail groceries, pharmacies, hospital pharmacies, dispensing physicians, institutions such as clinics and nursing homes, etc.
Distributor/wholesale level	This includes all distribution/wholesale levels between the manufacturer and / or importer and retailer

4.3.3. **Timelines for Effective Recall System**

Based on the category of risks involved, timelines are defined. The timelines defined are for the initiation of the recall procedure to commence from the receipt of information as notified by the Drug Regulatory Authority of Nigeria (NAFDAC) under statutory recall or voluntary recall by the manufacturer on its own. Details are given as under:

Class of Recall	**Initiation Time (From the time of identification of Defect)**	**Time to ensure Physical Recall from initiation**
I	<48 hours	Max 7 Days
II	<48 hours max 72 hours	Max 21 days
III	<48 hours max 72 hours	Max 30 days
V (Caution in use notice)	<48 hours max 72 hours	N/A

4.4. **Recall Strategy**

As the information related to the defective medical starts assembling, MAH will devise and discuss the proposed recall strategy and the recall classification with the NAFDAC (The Director, PMS on Risk Assessment and Recall of SF products). Any factor that may affect the duration of recall should also be communicated by the MAH. The proposed recall strategy must be approved by NAFDAC before implementation. The actual implementation of the recall includes the use of the basic steps which are summarized below, and these will be common to all strategies:

i. Indicate the proposed level in the distribution chain to which the recall is extending, if the recall only extends to the wholesale level, the rationale of not recalling the retailing level should be explained.
ii. In case of consumer-level recall, additional information such as the list of points of sale, etc. should also be provided.
iii. Indicate the method of notification (e.g. phone, email, etc.).
iv. Indicate how the message of recall will be delivered to customers e.g. press releases or recall letters etc. and if the MAH has a website, it should consider posting the recall notification on it as an additional method of recall notification.
v. Report on what the customers have been instructed to do with the recalled product.
vi. It is necessary for the recalling firms to know the name and title of the recall contact person for each of its consignees. Addressing a recall letter to a recall contact person will expedite the recall process and reduce the potential for the recall letter to get misdirected.
vii. If the product is to be returned, explain the mechanics of the process.

viii. Explain if the recall creates a market shortage that will impact the consumer.

- Suggest that MAHs conduct mock recalls periodically to test their recall strategies, ensuring they can be executed effectively in the event of a real recall in line with Q10 (Pharmaceutical Quality System).

5.0. Recall Communication To Remove Defective Products From Market

5.1. Methods of Communication to be Adopted

The MAH shall adopt the best approaches for effective communication of recall alerts to the targeted audience. Additionally, NAFDAC shall also issue recall notices to the manufacturer and recall alerts for the public and healthcare professionals. The following methods are to be adopted by the manufacturer and NAFDAC for effective communication:

Communication Method	Recall Classification
Recall letters/Notices (by both NAFDAC and MAH)	Class I, Class II and III
Press Release (only by MAH)	Class I or Class II (where appropriate)
"Caution in use" notice (only by NAFDAC)	Class IV only

- Expand the methods of communication to include modern digital channels such as social media, mobile apps, and SMS alerts, which can reach a wider audience quickly in line with ICH E2E (Pharmacovigilance Planning).

5.2. Recall letters

Recall letters are the most used tool for effective communication by the MAH with the distribution network, pharmacies/retail outlets, and healthcare professionals.

5.2.1 In case of a statutory recall, NAFDAC shall issue a recall letter to the MAH, informing them regarding the problem identified in the product and directing them to recall the defective product from the market.

5.2.2 In response, the MAH will issue a recall letter throughout its supply chain for effective recall of the defective product. However, in the case of a voluntary recall, the MAH issues initial information throughout its supply chain and informs NAFDAC.

5.2.3 A recall letter must be on the MAH's letterhead containing comprehensive information including a factual statement for the reason of recall together with the specific details to allow easy identification of products. A recall letter should also include the issuing date and signature along with the title and name of the signatory. A specimen recall letter is provided in **Annexure III**.

5.2.4 The recall letter may be sent via email, other electronic communication channels, or post. A recall letter may include;

i. **Description of the Product:** Brand Name; DRAP Registration/Enlistment Number; Name of Registration/Marketing Authorization holder; Name of manufacturer; Pack size; Dosage form; Batch number(s) and Expiry date.

ii. **Reason for Recall:** The reason for the recall should be concisely explained. It should be clarified that any further distribution or use of the product must stop immediately.

iii. **Contact Details:** The Licensee should identify a helpline for inquiry.

5.3. Press Release

5.3.1. Press releases are the responsibility of the licensee and are issued to the public for disseminating information about hazards categorized as Class I and where appropriate, Class II. This is in line with ICH E2E (Pharmacovigilance Planning) which emphasizes the importance of timely and accurate communication with the public regarding product safety issues, particularly for high-risk recalls.

6.0. Progress Monitoring, Evaluation Of Recall And Follow-Up Actions

6.1. Responsibilities of MAH and Role of Management

6.1.1. MAH is primarily responsible for carrying out the recall action and ensuring compliance with the recall procedure.

The MAH is responsible for developing an effective recall system and maintaining all records that will assist in recalling a product from the market in line with ICH Q7 (Good Manufacturing Practice) which emphasizes the importance of record-keeping to ensure traceability and accountability during recall operations.

6.1.2. Generally, all manufacturing and distribution records should be kept for two years after the transaction date or one year after the batch expiration date, whichever is longer.

MAH shall retain records of complaints received about each product in line with ICH Q10 (Pharmaceutical Quality System) supports the need for thorough documentation of complaints and follow-up actions to ensure continuous product quality and safety. Complaints should be examined appropriately by the nominated technical person and any subsequent action taken should also be documented and shown in the records.

6.1.3. To check the effectiveness of the recall system, a Mock recall shall be carried out for at least one batch of any product, dispatched for sale

where maximum distributors are involved in line with ICH Q10 (Pharmaceutical Quality System).

6.1.4. During mock recall traceability shall be performed for at least, one of the raw materials used in the batches identified for mock recall. Records of such mock recall should be maintained by the QA Head of the MAH and presented to the Drug Inspector when required/inquired. The following are the general responsibilities of the management of MAH:

Management Position	**Responsibility**
Director/CE	To monitor and ensure effective recall.
QC/QA Head	• Informing the management in writing about any product defect that may require recall. • Informing NAFDAC immediately after the recall decision is made. • Issuance of recall notice to all distributors/ marketing companies. • Overseeing the system for receiving, verification, quarantining, segregation, and securing of recalled stock. • Labelling of the recalled stock. • Investigating the incident which resulted in a product recall. • Write a report on the recall and submit it to DG, NAFDAC for the attention of the Director PMS**.** • Liaise with the Director, Investigation and Enforcement Directorate on the destruction /Disposition of the recalled stock as per the SOP of the firm.
Warehouse Head	• Receipt, verification, quarantine/ segregation, and secured storage of recalled stock under lock & key. • Informing QC/QA about the recalled goods. • Providing support during recall investigation.
Distributor/Marketer	• Ensure that any defective batches of products are removed from the market within the specified time frame according to the recall classification. • Co-ordinate with Wholesalers/retailers for the recall of batch(es) in the market
Wholesalers/Retailers	• To immediately quarantine the defective batch or batches of the product upon receiving the recall information. • Co-ordinate with consumers to recall the batch(es) in the market.

6.1.5. Introduce key performance indicators (KPIs) to measure the effectiveness of recall activities, such as the speed of response, the percentage of products recalled, and stakeholder satisfaction in line with ICH Q10 (Pharmaceutical Quality System)

6.1.6. Recommend that MAHs conduct a post-recall review to identify lessons learned and make improvements to their recall procedures, reducing the likelihood of similar issues occurring in the future in line with ICH Q10 (Pharmaceutical Quality System).

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6.2. Recall Reconciliation Report

After the completion of the timeframe of recalling the product, or at other agreed intervals following the direction of the Director, PMS, the licensee shall submit an interim and final report to monitor the progress of recall implementation.

6.2.1. Interim Report

The interim report should be submitted to the Director, PMS as soon as possible from the commencement of the recall, keeping in mind the timelines defined according to the class of recall. The following should be the contents of the interim report:

i. Reason of recall.
ii. When the recall notification was issued, and which communication channels were utilized?
iii. Number of distributors/firms/institutions etc., to whom the defective product(s) was supplied.
iv. Number of responses received from them.
v. Names of entities that did not respond to the licensee for recall notification.
vi. Quantity of stock returned till report date.
vii. Estimated time frame for the completion of the recall.

6.3. Final Report

A final report should be submitted to the Director, PMS within the defined timeline and the following information should be provided in the final report:

i. Reason for recall.
ii. Details of Actions taken by the Licensee.
iii. Extent of distribution of the relevant batch across the country and export
iv. Quantity of stock returned, corrected, outstanding.
v. Quantity of stock consumed.
vi. Quantity of stock not located.
vii. Date of recall completion.

6.4. Responsibilities of the Drug Regulatory Authority of Nigeria (NAFDAC)

6.4.1. To ensure an effective recall, NAFDAC shall review the information and recall strategy provided by the firm, suggest changes including the issuance of a public announcement or alert, assess the health hazard presented by the recalled product, and monitor the classification of the recall, and if required may re-assign the classification. NAFDAC will issue public announcements on a firm's recall and post information about recalls on NAFDAC's official website: www.nafdac.gov.ng NAFDAC may also provide recall information to the Ministry of Health and to Foreign Governments/Authorities (Importing or Exporting countries), if required. Also, NAFDAC should report the product on the WHO Global Surveillance and Monitoring System (GSMS) platform.

6.4.2. When a firm refuses to recall after being requested or ordered to do so by NAFDAC or the Authority has reasons to believe that the firm's recall strategy is not effective, or is not being implemented effectively, Regulatory actions will be taken as recommended by the Director General or the Director, PMS or by the relevant committee for the purpose in line with ICH Q10 (Pharmaceutical Quality System) which supports the need for regulatory oversight.

6.4.3. The role of the Director General, Director, and inspectors in a recall is to assess the adequacy of the MAH's actions on the recall of the product and to monitor the progress and effectiveness of the recall till appropriate disposal of the recalled product and the closure of recall.

6.4.4. During the investigation of a problem or root cause analysis, the Director of PMS may recommend that inspectors from the Drug Evaluation and Research (DER) Directorate, along with a panel of experts, may conduct a sampling of the product being recalled, if necessary, to further identify the root cause and its impacts. This is in line with ICH Q10 (Pharmaceutical Quality System) which supports the use of root cause analysis and expert evaluation to identify and address the underlying causes of product defects that lead to recalls.

6.4.5. It is also the role of NAFDAC to ensure that product recall is not used as a promotional means by any manufacturer/importer and such action shall be deemed as contravention of conditions of advertisement.

6.4.6. In case of reports issued or recalls initiated by international Agencies, NAFDAC will issue a recall alert for the public and a recall letter to MAH, overseeing the progress of the recall, keeping a record of activities being performed, and keeping a log of said recall.

6.5. Evaluation of the Recall

6.5.1. The purpose of the evaluation is to check the effectiveness and verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate

actions for the removal of the defective products in line with ICH Q10 (Pharmaceutical Quality System).

6.5.2. The recalling firm will be responsible for conducting effectiveness checks and will include these in the final report submitted to NAFDAC.

6.5.3. The recalling firm, as well as NAFDAC itself or its field offices, may also contact the firm's customers to ensure that the recalling firm and its consignees are fulfilling their recall responsibilities. If NAFDAC determines the recall to be ineffective, the recalling firm will be asked to take appropriate actions, including re-issuing recall.

6.6. Follow-Up Actions

6.6.1. The follow-up action may consist of a check on the effectiveness of a recall, an investigation of the reason for the recall, a root cause analysis, and remedial action taken to prevent the recurrence of the defect in line with ICH Q10 (Pharmaceutical Quality System).

6.6.2. The MAH/representative of MAH/QA Head of MAH shall monitor the recall process of the product/batch to determine whether the recall is progressing satisfactorily in line with ICH Q10 (Pharmaceutical Quality System).

6.6.3. The stocks of recalled goods shall be placed under "Quarantine" and stored separately under lock and key in a secure area until final decision in line with ICH Q7 (Good Manufacturing Practice).

6.6.4. Wherever required, the QA head of the MAH shall perform the physical inspection of recalled goods and collect samples 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 MAH, on "Investigation of Non-conformities" to identify the root cause of the failure and initiate corrective and preventive actions (CAPA) in line with ICH Q10 (Pharmaceutical Quality System) and ICH Q7 (Good Manufacturing Practice).

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

6.6.6. If the cause of recall is established to be a quality issue associated with any of the raw materials used, then the traceability of that material shall be established in all the product(s)/batches in line with ICH Q7 (Good Manufacturing Practice).

6.6.7. Based on the conclusion of the investigation findings, the QA Head of MAH/representative of MAH shall forward the investigation report along with corrective and preventive action and appropriate disposition plan of the batch(es) of recalled goods as per destruction/disposition SOP of MAH to the Directorate of QA&, Director, PMS NAFDAC.

Disposition/destruction shall be done in the presence of the Investigation and Enforcement Directorate, or a team specified for the purpose by NAFDAC.

6.6.8. The Director, PMS shall write a memo to all the Zonal and State Offices to carry out surveillance on the product/batches and if found mop up from the circulation.

6.7. Recall Closure

6.7.1 A recall will be closed when the Director, PMS determines that all reasonable efforts have been made to remove the product from circulation following the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made according to the degree of hazard of the recalled product.

6.7.2 The Director, PMS shall respond to the recall reports submitted by the recalling firm make his observations known to the firm, and direct the firm to liaise with the Director, I&E for destruction in line with ICH Q10 (Pharmaceutical Quality System).

7.0. Annexures

Annex-I	Recall Assessment Form
Annex-II	Recall log
Annex-III	Recall letters / Notice to distributors/marketing company/retailers

8.0. References

In developing these guidelines, guidance documents referred are.

i. Schedule B-II of the Drugs (Licensing Registering and Advertising) Rules, 1976
ii. PIC/S Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects
iii. WHO Recall Guidelines
iv. A Guide to Defective Medicinal Products 2021 – MHRA UK
v. FDA Voluntary Recalls - 21 CFR

ANNEXURES ANNEXURE-I

Recall Assessment form

(To be filled by MAH on their letterhead)

To, Recall Ref. No. _____ Date: _____

Recall information	**Information provided by MAH**	**Comments of The Director, PMS on Risk Assessment and Recall of SF Product** (For NAFDAC use only)
Origin of report		
Name of person/organization reporting the problem (State whether it is a complaint, quality defect, lab report, voluntary or statutory)		
Date of report		
Name of recalling firm		
The physical address of the recalling firm		
Telephone number of recalling firm.		
Alternate number of recalling firms.		
E-mail address of recalling firm		
Name of nominated person of recalling firm		
Product(medicine) details		
Name of product affected		
Registration number		
Dosage form		
Strength		
Pack size/type		
Batch number		
Date manufactured		
Expiry date		
Total quantity before distribution		
Quantity released for distribution before the recall		
Date of distribution (Annex list of distributors along with date of distribution – Provide separate list for local and overseas distribution)		

Nature of defect		
Source of problem		
Details of problem		
Number of complaints received (if any)		
Action taken so far (if any)/ Proposed action and its urgency		
Type of hazard/health risk and assessment of risk to the user		
Proposed recall classification and level of recall		
Other relevant information		

*This form should be submitted to NAFDAC within the timelines prescribed in this document.

_____ Signature of contact person & Stamp of MAH

ANNEXURE-II
RECALL LOG (RECONCILIATION FORM)

(To be filled by the MAH on their letterhead)

Name of Manufacturer/Importer	
Contact person name and Phone number	
Recall Ref. No.	
Time and Date of Recall Initiation	
Product name	
Batch/Lot No. Mfg. date	
Exp. Date	
Reason of recall	
Recall Classification (Proposed by licensee)	
Quantity Produced / Batch Size	
Undistributed quantity in possession	
Quantity Distributed	
Quantity Returned / Recalled	
Percentage of recall	
Remarks (If any	

_____ Signature of contact person & Stamp of License

ANNEXURE-III
SAMPLE RECALL LETTER TO BE ISSUED BY LICENSEE TO DISTRIBUTORS / MARKETING FIRM / RETAIL OUTLETS ETC.

(To be issued by MAH on their letterhead)

To, Recall Ref. No. _____ Date: _____

Please stop further distribution/sale of the below-mentioned product/batches with immediate effect. Kindly recall the stocks of these batch(es) from the market and return them immediately

Product Details (Name, Strength, Dosage form, Pack size, Reg. or listed. No.)	Batch/Lot No.	Mfg. Date	Exp Date

Reason of Recall_____

Sign and Stamp of MAH