Ethiopian Food and Drug Authority

Guidelines for Medical Device recall

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Contents

ACRONYMS

EFDA	Ethiopian food and drug authority
EU	European Union
ICD	Implantable Cardioverter defibrillator
IMDRF	International medical device regulators forum
IVD	In vitro diagnostics
US FDA	United States Food and Drug Authority
WHO	World Health Organization
SAPHE	Sustaining and Accelerating Primary Health in Ethiopia

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1. INTRODUCTION

EFDA is responsible to regulate the safety, quality and performance of the medical device that are made available for public use as mandated by Food and Medicine Administration Proclamation No. 1112/2019. Ensuring the safety, quality and performance of medical device is basically the prime responsibility of manufacturers, importers or wholesalers. When medical device are suspected of being potentially harmful to users due to their non-conforming quality, safety or performance or violating a national law, they may be subjected to a recall or field safety corrective action. Medical device recalls are normally conducted on voluntary basis by the manufacturer or its authorized representatives. However, the Ethiopian Food and Drug Authority (EFDA) may also order to recall medical device where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, under article 4(4) of proclamation 1112/2019 that gives the authority the power to order the disposal or recall of a medical device that is not in compliance with the proclamation or other subsequent laws. In addition, article 65(7) decrees that "Where a regulated product is in contravention of applicable laws and, the use or exposure to this product will have adverse health consequences or would result in death the responsible person shall be ordered to recall their marketed products and to immediately cease distribution".

In addition to the various regulatory measures being implemented by the authority, ordering the recalling of non-confirming devices is one of the systems that is applied to protect the public from medical devices that are potentially harmful to patients and health professionals due to their non-conforming quality, safety or performance.

Accordingly the Authority may order a recall of non-conforming medical device based on confirmed adverse event reports, complaint, or based on post marketing surveillance results and when recognizes that serious injury has happened may happen to the public by the use of or exposure to medical device.

Therefore, this guideline is developed to provide guidance to medical device manufacturers, its authorized representatives, importers, wholesalers and other concerned stakeholders on how to undertake, manage, classify and report a recall. It also provide guidance to EFDA as well as the manufacturer or its authorized representative on the actions to be taken for non-conforming medical device in a reasonable time frame.

2. DEFINITIONS

Medical device: - Any instrument, apparatus, appliance, material or other Article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Recall: - means any action taken by the manufacturer, importer or distributor of the device whether voluntarily or with the Authority's order to remove or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: - may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its safety, quality or performance characteristics or may not meet the Authority's regulatory requirements.

A recall may include:

- removing a medical device from the market
- instructing customers to stop using a medical device and destroying remaining units in stock
- doing an on-site correction of a medical device
- advising users of a device about a problem or potential problem

- supplying different labelling (which may include updates to instructions or manuals)

Manufacturer:- The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Authorized Representative: - It is a natural or legal person that receives a written mandate from a manufacturer or license holder of another jurisdiction to act on his behalf for specified task including the obligation to represent the manufacturer in its dealing with regulatory requirements.

Distributor or wholesaler: - Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user. More than one distributor may be involved in the supply chain as a distributer.

Importer: - It is a natural or legal person in the supply chain who is the first in a supply chain to market or available in the country or jurisdiction where it is to be marketed.

Product defect:-A non-conformity to a specification confirmed by laboratory analysis or a suspected deficiency which may produce an impact either directly or indirectly on the continuing quality, safety and performance of medical device.

Nonconformity: - means the no fulfillment of a specified requirement.

Authority: - means Ethiopian food and drug authority

Withhold:-Temporary suspension of sale or use of a medical device without recall from the market, until its quality, safety and performance is checked.

Statutory recall:-A recall initiated by Ethiopian food and drug authority (EFDA) after a notification of medical device defect is identified.

Voluntary recall: -A recall initiated by a medical device manufacturer or its authorized representative after a notification of medical device defect is identified.

Stock Recovery: - is correcting and removing any device that is yet to get marketed or one that is still under the direct control of the manufacturer. For instance, such a device could still be found

on the manufacturer's premises without having been released for use or sale of any portion of the lot, or model among other relevant units involved in the removal or corrective action.

Rapid alert system:-A system that is used to transit alerts on recalls to relevant stakeholders, and whose urgency and seriousness cannot permit delay in transmission than given in respective timelines.

Product License Holder:-Is the person or business which could be the manufacturer of a medical device and has the primary responsibility for the supply and distribution of the product in Ethiopia.

Recalling firm: - means the firm that initiates a recall. It is usually the firm that has primary responsibility for the manufacture/import and marketing of the product to be recalled.

Recall strategy: -means a planned specific course of action to be taken in conducting a specific recall, which addresses itself to matters such as the depth of recall, need for public warnings, and extent or effectiveness checks for the recall.

Corrective and preventative action (CAPA):- Action taken to eliminate the causes of non-conformities or other undesirable situations and action taken to prevent further reoccurrence of such non-conformities.

3. SCOPE

This guideline is applicable to all medical devices that are marketed in Ethiopia.

4. OBJECTIVES

The general objective of this guideline is to help anyone who is engaged in medical devices supply and use understand and comply with the requirements of medical device recalls with an ultimate intention of protecting the public health by ensuring that the recall operations are efficiently and effectively carried out.

It also provides guidance and applicable requirements for recall process, recall classification and levels to the entities who get involved in recalling of nonconforming medical devices.

5. CLASSIFICATION AND LEVEL OF RECALL

5.1. Health Hazard Evaluation and Classification of recall

An evaluation of the health hazard presented by a device being recalled or considered for recall is conducted by the authority by taking in to account, but need not be limited to, the following factors:

- Whether any disease or injuries have already occurred from the use of the device
- Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard
- Assessment of hazard to various segments of the population, e.g., children, surgical patients, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
- Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed
- Assessment of the likelihood of occurrence of the hazard and
- Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

These determinations should be used as the basis for assigning the recall classification by EFDA according to the potential hazard of the defect and the level of risk that posed to the public, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

5.1.1. Class I recalls

Are recalls under situation in which there is a reasonable probability that the use of, or exposure to, a violative device will cause serious adverse health consequences or death.

Examples of class I recalls are

a) hot/cold gel pack contains a toxic substance that could be ingested accidentally by a young child

b) higher fracture rates for implantable cardiac leads that may result in Implantable Cardioverter Defibrillators (ICDs) not providing effective therapy, resulting in serious injury or death
c) software defects resulting in linear accelerators delivering the wrong radiation dose or delivering to the wrong location
d) hardware or software failures in ventilators resulting in shut down during its use
e) a false result on an IVD test for a medicine with a narrow therapeutic range that could lead to an overdose, causing permanent injury
f) False negative result on an IVD test for a serious or highly contagious disease.

5.1.2. Class II recalls

Are recalls under a situation in which use of, or exposure to, a violative device may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Their defect could cause illness or mistreatment, temporary adverse health consequences to the public but are not Class I.

Examples of Class II recalls are

a) microbial contamination of a personal lubricant
b) higher than expected rate of revision surgeries due to mechanical failures to one of the components in a total hip, knee or shoulder implant
c) infusion pumps giving visual or audible alarms due to software or hardware issues resulting in delay in infusion
d) omission of precautionary information on procedures that could cause complications for the patient, such as omission from the Instructions for use for a catheter of a precaution for certain procedures that could cause complications in its removal
e) An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment.

5.1.3. Class III recalls

Are recalls under a situation in which use of, or exposure to, a violative device is not likely to cause adverse health consequences and significant hazard to health, but withdrawal may be initiated for other reasons.

Examples of Class III recalls are

a) a disinfectant has been mislabeled with an expiry date that predates the actual expiry date
b) the outer packaging of a medical device indicates a different size to that which is actually in the supplied in the box, but it would be obvious to the clinician that the device was the incorrect size and the size isn't among the critical performance characteristics of the device.
c) An IVD reagent is causing calibration failures towards the end of its shelf life, but there is no effect on patient results.

Generally, Class I and Class II recalls are considered to be urgent safety-related recalls that must be reported to the authority for further evaluation and investigation while class III recall is considered to be non-safety-related recalls.

5.2. Level of recall

The level (or depth) of a recall is based on the distribution of non-conforming medical device. In determining the recall level, the principal factors to be considered are the significance of the hazard (if any), the channels by which the defective medical device have been distributed, and the level to which distribution has taken place. There are three levels of recall.

5.2.1. Level I

Importer or wholesale level which includes all parties involved in importer or wholesale distribution channels.

5.2.2. Level II

Retail level which includes:

a) All public and private hospital pharmacies.
b) Retail pharmacies.
c) Clinical investigators and the institutions in which clinical investigations are performed.
d) Medical, dental and other health care practitioners.

e) Nursing homes and other related institutions.

5.2.3. Level III

Consumer level which is used where there is a significant risk of harm to the consumer or users and includes Patients and other consumers.

A recall should be assigned an appropriate level depending on the nature of the defect, the distribution network of the product, and the extent of distribution.

6. TYPE OF RECALLS

Based on who initiates it, recalls may be of two types, voluntary and mandatory. Medical device recalls are normally conducted voluntarily by the manufacturers or their legal representatives. Where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, the authority may issue a recall order to the manufacturer or legally authorized representative. The manufacturer or its representative may consult with the authority regarding whether the suspected device intended for human use would possibly cause serious adverse health consequences or death.

6.1. Voluntary Device recall

This types of recalls are undertaken voluntarily and may be initiated at any time by manufacturers or legal representative. Voluntary recall is an action that takes place because manufacturers or legal representative carry out their responsibility to protect the public health and well-being from devices that present a risk of injury or gross deception or are otherwise defective. Such a recall is usually undertaken before the authority initiates an administrative measure or court action for removing or correcting violative devices that have been distributed.

Voluntary recall does not include market withdrawal or a stock recovery. A market withdrawal is a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the authority or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

6.2. Mandatory Device Recalls

Any firm that has primary responsibility for the manufacture and marketing of the medical devices may be directed by the authority at any time to recall defective device that presents a risk of injury or gross deception or that violates any of the applicable Authority's regulatory requirements. A recall order is issued under instances where the manufacturer or its legal representative or importer fails to voluntarily recall a device that is a risk to health. If the authority confirms that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death it may issue a cease distribution and notification order requiring the manufacturer or its legal representative or importer to immediately:

- cease distribution of the device;
- notify health professionals and device user facilities of the order; and
- instruct these professionals and device user facilities to cease use of the device

The manufacturer or its legal representative will have an opportunity for a regulatory hearing or to provide a written request to EFDA asking that the order be modified, vacated, or amended. The authority may modify or amend the order that requires a recall of the device based on available scientific evidences.

7. RECALL STEPS

The manufacturer or its legal representative should have a procedure that defines the major steps to be followed during recall of any non-conforming medical device. The firms should also maintain the records for the evidence of the procedure's implementation for the devices that have been recalled. The procedure should at least include the seven stages set out below.

7.1. Identifying the need to initiate a recall

Manufacturers or its representative should initiate a recall action if they receive or claim the device (including its labeling) is non-conforming or potentially defective and may be hazardous to public health based on the result of the necessary investigation. The manufacturer or its authorized representative should establish an arrangement to collect information regarding non-conformity or deficiency with a device through complaint investigations, inspections, or internal quality control

testing or audits (e.g. for a non-conforming product). It is the responsibility of the manufacturer or its representative to determine the level and classification of recall and take all the necessary actions required to correct problems (e.g. investigating a complaint or non-conforming product, taking corrective or preventive actions) or remove the device from the market. Defectiveness may be related to:

a) Design deficiencies
b) Component defects or failures
c) Labeling and packaging problems
d) Manufacturing problems
e) Software errors
f) Improper shipping, installation or servicing
g) Storage, transportation, and etc.

7.2. Recall notification

As a general rule, the period for the notification of recall should take account of the class of the recall. Before or upon initiating a recall, the manufacturer or its authorized representatives or importers of the non-conformity device should notify to EFDA as per annex I, health professionals and the public for class I recalls within **24** hours after identifying the problem or receipt of complaints for investigation and not to use it. If the non-conforming medical device poses a potentially significant hazard to the public during weekends or public holidays, the manufacturer or its authorized representatives or the user may immediately initiate actions by itself which could include precautionary measures to block or quarantine the non-conforming medical device without notifying the authority. However, within **72** hours the manufacturer or its authorized representative should notify the case to the authority by the most rapid means available (e.g. direct verbal communication, telephone, fax, or email) and should be promptly followed up in writing; but in cases, where more than one company has imported or distributed the affected devices in Ethiopia, each company that imported or distributed the non-conforming devices are required to report individually. In addition, Class II and Class III recalls should normally be notified to the Authority within 48hrs and 72hrs respectively after the problems are identified or the complaints are received. The notification should include, but not limited to, the following minimum information:

a) The name of the defective device

b) Name and address of the defective device Manufacturer and importer
c) Model number or lot /batch number and any other means of identification.
d) The total quantity of the defective product originally manufactured or imported
e) The total quantity of the defective product that had been distributed in the country
f) Area of the distribution of the defective product in the country
g) The quantity of the defective product present on hand.
h) The reason for initiating the recall and etc.

7.3. Initiation of a recall

Once the device problem has been identified and notified to the authority, the manufacturers or its authorized representative who are ultimately responsible for the device's safety, quality and performance should initiate recalls immediately after the commencement of the notification. But, manufacturers might also be directed by the authority to initiate device recall based on regulatory inspection findings and laboratory test results carried out on samples of medical devices obtained from post marketing surveillance, complaints come from the public or safety alerts issued by WHO, IMDRF and/or stringent regulatory authorities (USFDA, EU, etc).

7.4. Developing recall strategy

The recalling firm should develop a recall strategy or equivalent detailed plan that takes into account the following factors as they apply to the individual circumstances of the particular recall:

- Results of health hazard evaluation
- Ease in identifying the product
- Degree to which the product's deficiency is obvious to the consumer or user
- Degree to which the product remains unused in the market-place
- Continued availability of essential products.

The recall strategy should be submitted to and reviewed by the authority for adequacy of a proposed recall strategy and recommendation for changes may be provided as appropriate. The recalling firm should conduct the recall in accordance with an approved recall strategy but need

not delay initiation of a recall due to pending review of its recall strategy. The recall strategy should address the following elements regarding the conduct of the recall:

- Evaluation of risk
- Depth of recall
- Public warning
- Timelines
- Effectiveness check
- Recall communication

7.4.1. Evaluation of risk

Recalling firms should establish recall strategy which defines how to evaluate the risk associated with a non-conforming device. The extent and type of the recall action depends on the hazards associated with using or exposure to the non-conforming device. When evaluating risk, firms should take into account:-

a) The nature and degree of the hazard
b) The nature of the particular population at risk
c) The size of the population at risk
d) The degree of the customer's competence in using the device
e) Customer awareness of the problem
f) Whether any disease, injury or death have already occurred from using the device
g) The probability that the issue will happen again
h) The user's ability to detect the problem

The recalling firm should perform a risk/benefit comparison using the results of its risk evaluation. It should use these results of risk evaluation to assign a health hazard classification (as class I, II or III) for the recall.

7.4.2. Depth of Recall

Depending on the product's degree of hazard and extent of distribution, the recall strategy should specify the level in the distribution chain and how far in the distribution chain the recall should

extend. The recall should extend to the appropriate level based on the type of device (including where and how it is used) and the risk it poses to the public and the recall may extend to the:

a. Importer or Wholesale levels
b. Retail levels
c. Consumer or user level (health care facilities, health care professionals)which may vary with product, including any intermediate wholesale or retail level;

7.4.3. Public warning

The recall strategy should ensure that public warning system is in place and serves the intended purpose of alerting the public that a product being recalled presents a serious hazard to health. This should be reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The authority in consultation with the recalling firm may issue such publicity jointly. When the recalling firm decides to issue its own public warning, it is requested to submit to the authority its proposed public warning and plan for distribution of the warning for review and comment prior to publicity of the issue. The recall strategy should specify whether a public warning is needed and whether it will issue as:

- General public warning through the general news media, either national or local as appropriate, or
- Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

Rapid alert to the public is usually reserved for hazards classified as Class I and, where appropriate, Class II, or situations where other means for controlling the hazard appear inadequate.

7.4.4. Timelines

The recall strategy should define time frames for key activities and when initial communication is not the sole recall action, detailed plan of estimated time frames for accomplishing the remaining actions should be set.

Based on the category of risks involved and depth of the recall, a factual time line of within **24** hours to a maximum of **48** hours is given for Class I recall. For class II recall up to maximum of **10** days and for Class III recall, whenever necessary, up to maximum of **20** days is allowed.

7.4.5. Effectiveness checks

The purpose of recall effectiveness checks is to verify that all consignees (at the recall depth specified by the strategy) have received notification about the recall and have taken appropriate action. Consignees may be contacted by personal visits, telephone calls, letters, or a combination thereof. Recalling firm may use different methods for conducting recall effectiveness checks. The recalling firm is responsible for conducting effectiveness checks, but authority may assist in the effectiveness checks where necessary and appropriate. The recall strategy should specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- Level A--100 percent of the total number of consignees to be contacted;
- Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
- Level C--10 percent of the total number of consignees to be contacted;
- Level D--2 percent of the total number of consignees to be contacted; or
- Level E--No effectiveness checks.

The authority may evaluate the effectiveness of the recall by inspecting the Recall records and, in some cases, by contacting a percentage of customers in the distribution list as a means of assuring that the consignee is carrying out its recall responsibilities. If the Authority finds the recall to be ineffective, the consignee will be asked to take appropriate steps, including re-issuing recall letters.

7.4.6. Recall communications

A recalling firm has primary responsibility for notifying the recall to their customers as well as the public. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. The recall strategy should define the method and content for all communications associated

with the recall. The letter and the envelope should be also marked: "urgent" for Class I and Class II recalls and, when appropriate, for Class III recalls. The authority might also announce a rapid alert to public for class I and class II recalls and the means of communication might be via mass media, press release, letter, telephone and official websites. All recall communications should meet the purpose of a recall which is to convey:

- That the device in question is subject to a recall with the reasons of recall
- That further distribution or use of any remaining device should cease immediately
- Where appropriate, that the direct account should in turn notify its customers who received the device about the recall
- Instructions regarding what to do with the device

In general, the recall communication should be written in accordance with the following requirements:

a. Be brief and to the point;
b. Identify clearly the product: description of the device, size, Model number, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
c. Explain concisely the reason for the recall and the hazard involved(i.e. the risks associated with its use), if any;
d. When appropriate, that further distribution or use of the remaining product must stop immediately
e. When appropriate, an indication for the customers who may have further distributed the device to forward the recall communication to their customers
f. Request for a prompt response to confirm receipt of the recall communication
g. Provide specific instructions on what should be done with respect to the recalled products; and
h. Provide a ready means for the recipient to report to the recalling firm whether it has any of the device, e.g., by allowing the recipient to place a collect call to the recalling firm.

The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication. A recalling firm is encouraged to discuss the recall letter with the authority prior to issuing the notification.

Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees.

All customers and competent authorities of all countries to which the medical device under recall might have been distributed should be informed promptly of any intention to recall the product because it is, or is suspected to be, defective, substandard, or counterfeit.

7.5. Recall status reports

The recalling firm should submit periodic recall status reports to the authority for progress evaluation and if necessary for subsequent market surveillance.

The frequency of the recall should be specified based on the relative urgency of the recall. However, the Authority expects the reporting interval to be maximum of two weeks unless otherwise instructed by the authority. Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

a) Number of consignees or customers notified of the recall, and date and method of notification
b) Number of consignees or customers responding to the recall communication and quantity of products on hand at the time it was received
c) Number of consignees or customers that did not respond (if needed, the identity of no responding customers may be requested by the authority)
d) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for
e) Number and results of effectiveness checks that were made
f) Estimated time frames for completion of the recall

Recall status reports should not be discontinued unless the recall termination is approved by authority. The Authority reserves the right to reject non fulfillment and delayed reports. Submission of the report may be by hardcopy, via email, fax or postal mail. For email submissions, a scanned copy of the completed hardcopy should be attached.

7.6. Collecting and quarantining the device

Where a recall is instituted by an entity other than the original manufacturer and/or marketing authorization holder, the original manufacturer and/or marketing authorization holder should be informed in the event of a recall. Consultation with the original manufacturer and/or marketing authorization holder should, where possible, take place before the recall is instituted. Information on a recall should be shared with the EFDA or appropriate regional regulatory bodies. If a recall of the original product is necessary because of a counterfeited device which is not easily distinguishable from the original device, the manufacturer of the original device and the relevant health authority should be informed.

Finally the manufacturer or its authorized representative should collect the non-conforming device from the market according to the timeline and should quarantine those products segregated from the normal until action is taken based on the risk assessment reports. Due to potential risks, any returned device should be controlled to prevent it from being further used or distributed.

The effectiveness of the arrangements for recalls should be evaluated at regular intervals.

All recalled medical devices should be stored in a secure, segregated area pending appropriate action.

Recalled medical devices should be segregated during transit and clearly labelled as recalled devices. Where segregation in transit is not possible, such device must be securely packaged, clearly labelled, and be accompanied by appropriate documentation. The storage conditions applicable to the device which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the device in question.

7.7. Evaluating recall effectiveness

The firm`s recall strategy should specify how to evaluate effectiveness of the recall. In most cases, firms can monitor the effectiveness of the initial notification through the level of customer response. Responses may involve written acknowledgement that the customer received, read and

understood the recall. Firms may also require customers to provide information about the status of affected devices. When the recall is complete, the recalling firm should evaluate its effectiveness. This evaluation should answer how many responses it has received following its notification process and how successfully did it complete corrective actions. Firms should evaluate the effectiveness of each action required under the recall (e.g. responses to the initial notice, corrections or returns).

7.7.1. Checking completion of recall

The manufacturer or its authorized representative should review all information collected from their customers after the completion of the recall to check that no more non-conforming device are available on their warehouse or on the market. Upon completion of the recall, firms should submit final report to the authority as per annex II. The authority might conduct further market surveillance to check no more non-conforming device are available on the market.

7.7.2. Corrective and preventive action

On completion of a recall, the manufacture or its representative should provide a report of the investigation on the problem, corrective action and details of the remedial action proposed to prevent a recurrence of the problem.

7.7.3. Device disposition

After the non-conforming devices are collected and quarantined in the warehouse, regulatory action should be taken (e.g. disposed or return to country of origin). In case of labeling problem, the device may not be disposed unless it has other additional defects. In such cases, the manufacturer should correct the labeling before re-marketing the devices for public use. Recalled medical devices disposal should be carried out in accordance with the Medical devices decommissioning and disposal guideline. For disposed device, the manufacturer or its authorized representative may request disposal certificates from the authority. In case where the device is returned to country of origin for disposition, the firm should submit shipment document to the authority.

7.8. Recall termination and closing

A recall should be terminated when the authority determines that all reasonable efforts have been made to remove or correct the device in accordance with 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 commensurate with the degree of hazard of the recalled device. Written notification that a recall is terminated will be issued by the authority to the recalling firm after the closing of recall.

8. RECORD KEEPING

The recalling firms must maintain documents (in written form) of distribution records and doing recalls. The type of document may be for each activity in a single procedure or use a number of procedures, depending on the structure of the firm`s quality management system. Records should be maintained to show that the procedures are being followed.

All records should be readily available to the designated person(s) responsible for recalls. These records should contain sufficient information on the medical device supplied to customers (including exported devices).

The progress of a recall process should be recorded, and a final report issued, which includes reconciliation between the amount delivered and the quantities of concerned devices/batches.

9. REFERENCES

1. *Proclamation No.1112/2019: Proclamation to provide for food and medicines administration, 2019*
2. *Pharmaceutical products recall guidelines of Ethiopia, EFDA, 2015*
3. *Australia therapeutic goods administration guidelines for medical device recall*
4. *GN-04: Guidance on Medical Device Recall, Singapore*
5. *Pharmaceuticals product recall guideline December 2019, Hong Kong SAR china*
6. *USFDA guideline for medical device recall*
7. *Medicine and Medical Device Recall Directive (Amharic version) No. 391/2013, EFDA.*

10. ANNEX I: RECALL NOTIFICATION FORM

RECALL NOTIFICATION FORM

DETAIL OF THE PROBLEM	
Name of the company	
Responsible person	
Address	
Phone number	
Email	
Nature of the problem	**□ Safety □ Quality □ Labeling □ Compliance Issue □ Other (specify)**
Date of receiving complaint	
Source of Complaint	**□ Patient □ Customer □ Retailer □ Self-inspection □Other:**
Proposed recall classification □ Class I □ Class II □ Class III	
PROPOSED ACTION (WITH AGREEMENT OF DEPARTMENT OF EFDA)	
Recall start date	**Proposed recall end date**
Proposed recall level □ Wholesale □ Retail □ Consumer	
Location of recall are	
Description of the problem (use separate sheet if space is inadequate	
Proposed recall strategy (use separate sheet if space is inadequate	

Name of the company----------

Responsible person----------

Signature----------

Date----------

11. ANNEX II: FINAL RECALL REPORT FORM

FINAL REPORT FORM

Details of the recalled products	
Name of the product	
Batch number or serial number	quantity
	Manufacturing date
	Expiry date
Reasons for recall	
Extent of Distribution	
Importer level or Wholesale level	
Retail level	
Customer level	
Quantity of distribution	
Quantity manufactured	
Quantity imported	
Quantity distributed	
Quantity exported	
Quantity on hand	
Action taken by the product owner	
Result of Recall	
Quantity of stock returned	
Quantity of stock consumed	
Disposal Plan	
Method of Disposal □ Destroy □ Return to overseas manufacturer □ Others, please specify:	
Details of the disposal method	

Name of the company----------

Responsible person----------

Signature----------

Date----------