



ETHIOPIAN FOOD AND DRUG AUTHORITY

**Guideline for Post-market surveillance of
Medical Devices**

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Abbreviation

| | |
|------|--|
| EFDA | Ethiopia Food and Drug Authority |
| eRIS | Electronic Regulatory Information System |
| FMOH | Federal Ministry of Health |
| FSCA | Field Safety Corrective Action |
| FSN | Field Safety Notice |
| GPS | Global Positioning System |
| IVD | In Vitro Diagnostic |
| NGO | Non-Governmental Organization |
| OOS | Out of Specification |
| QC | Quality Control |
| QMS | Quality Management system |
| RHB | Regional Health Bureau |
| SOP | Standard Operating Procedure |
| WHO | World Health Organization |

1. Introduction

Medical device that has been authorized by the Ethiopian Food and Drug Authority and marketed in the country must continue to meet the quality, safety and performance requirements and standards as long as it is in use.

Pre-market conformity evidence for the product quality, safety and performance generated and submitted by the manufacturers are evaluated by the Authority before the medical devices are placed on the market for use in order to reduce risk to the public. Decisions with regard to reducing risks and residual risk acceptability are made based on risk management principles. However, issues might arise after the medical device is placed on the market. Hence, it is important to collect and analyse information on or, as appropriate, test samples of the medical device after it is marketed for monitoring its safety and performance. This would be an opportunity for the manufacturers as it allows them early detection of any undesirable effects, identify residual risks, making a correction and/or field safety corrective actions and notifying the users and the regulatory body. In addition, the outcomes of the post market surveillances will be very useful for the regulatory bodies to take appropriate timely actions to protect the safety of the patients or users.

Post-market surveillance(PMS) is the collection of information on safety and performance of medical devices after they have been placed on the market. PMS enables the marketing authorization holder, importer, wholesaler, user and/or the regulatory authority to consider necessary actions if the risk of continuing to use the device outweighs its benefit.

Accordingly, EFDA is mandated by article 38 of the Food and Medicine Administration Proclamation 1112/2019 which requires the manufacturer and importer to perform periodic monitoring of the quality, safety, and effectiveness of its manufactured or imported medical device by performing a post marketing surveillance that would enable it to continuously monitor medical device. The article also mandate the authority to conduct periodic PMS on medical device circulated throughout the country and as appropriate request the manufacturer or importer to cover the cost of PMS on their manufactured and/or imported medical devices. In addition, the article highlight the manufacturers and the importers are responsible for the damage caused by quality and safety problem of their product.

This guideline focuses on activities related to the planned testing of devices on the market, and conducting regular market surveys of technical documentation to ensure their conformity with the products` initial claims during marketing authorization by reviewing of marketed products

claims, labeling, and literature used for promotion and advertising as part of regular audits of manufacturer, importer, wholesalers or user facilities to ensure that medical devices used in the market continue to meet safety, quality and performance requirements.

The requirements in this guideline are basically meant to ensure that all marketed devices remain safe and effective (perform as intended by the manufacturers) and all required information are gathered, analysed, recorded, and provided as per the regulatory requirements of the proclamation 1112/2019.

All users of this guideline are kindly requested to forward their valuable comments and suggestions to the Ethiopian Food and Drug Authority, via P.O.Box 5681, Tel. 251-11 552 41 22, or email: contactefda@efda.gov.et, Addis Ababa, Ethiopia.

2. Definitions

Authority is Ethiopian Food and Drug Authority

Adverse Event is a product defect (i.e. malfunction or failure, deterioration in characteristic or performance, in adequacy of labelling or off-instruction for use) that directly or indirectly has led or might have led to a medical consequence including death or serious deterioration in the state of health of the patients, users or another person. It is synonyms with incident.

Conformity assessment is determining whether the relevant requirements in legal and technical regulations or standards are fulfilled.

Correction is an action taken to eliminate any detected non-conformity

Corrective action is an action to eliminate the cause of a detected nonconformity or other undesirable situation and to prevent recurrence.

Field safety corrective action (FSCA) is action taken by the manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

Field safety notice (FSN) is a communication sent out by a manufacturer or its representative to the device users in relation to an FSCA.

In vitro diagnostic medical device (IVD) is a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Lot is defined amount of material that is uniform in its properties and has been produced in one process or series of processes.

Post-market surveillance is a systematic process of collecting, analysing, and testing samples of medical devices that have been placed on the market as well as collecting relevant information through market surveillance and measures taken to ensure the devices compliance with the requirements set out in the relevant legislation.

Preventive action is action to eliminate the cause of a potential nonconformity or another user

3. Scope

This guideline is applicable for post market surveillance for safety, quality, and performance monitoring of all medical devices, including IVDs, placed on the Ethiopian market. Borderline products that are categorized as medical devices and are subject to medical device regulatory pathways are also within the scope of this guideline (please refer to ‘*Guidelines for Borderline Medical devices*’ to make appropriate determination of the categories). The guideline covers the planning of PMS, conducting of market surveillance, sampling and laboratory quality testing of medical devices placed on the market of the country and recommendations for regulatory action.

4. Objectives

The objective of this guideline is to guide risk-based market survey on safety, quality and performance of medical devices placed on the market, whose information are reviewed or sampled at various levels of the supply chain with the aim of assessing their compliance with the national or adopted international standards or manufacturers requirements for storage, distribution and use; and ultimately propose appropriate regulatory actions.

5. Responsibilities

5.1. The Authority (EFDA)

1. Initiate the overall survey management, coordinate activities and collaborate with different stake holders such as MOH, Health Bureaus, regional regulatory bodies and development partners as well as manufacturers, importers, wholesalers and users.
2. Coordinate testing using a risk-based approach, strive to collect other forms of post-market intelligence and undertake appropriate and timely regulatory action.
3. Create awareness among users and clients/patients about the importance of reporting detected issues.
4. Enforce manufacturers to develop a system to receive feedback directly from users and their patients/clients, and to forward it to the authority.
5. Conduct a risk assessment when forwarding feedback.
6. Collect manufacturer’s/importer’s investigation report and review for evidence of documented procedures, timelines and scientific rigour.

7. Undertake regulatory actions based on PMS report and manufacturer's investigation report.
8. As appropriate, share information with local stakeholders, other countries regulatory authorities, relevant international organizations such as WHO and other development partners.
9. Establish national PMS management task force composed of relevant stake holders, which is responsible for coordination of the PMS. The roles and responsibilities of the PMS task force would be detailed in the specific protocol to be developed or revised on yearly basis.

5.2.Regional Regulatory Bodies

1. Collaborate with EFDA and coordinate PMS activities planned to be undertaken in their respective regions.
2. Take appropriate actions based on PMS report in their respective mandate.
3. Share information regarding PMS findings to relevant stakeholders within their respective region.

5.3.Medical device manufacturers

The manufacturers are responsible to:

1. Perform a post marketing surveillance to continuously monitor their medical device and timely report the findings as required by article 38(2) of proclamation 1112/2019.
2. Establish a documented procedure to conduct PMS and provide early warning of quality problems and for input into corrective /preventive action processes.
3. Continue collecting and evaluating information on the medical device during production and post-production to meet requirements for the monitoring of products and processes and to ensure the residual risks remain acceptable with respect to benefits.
4. Set appropriate procedure that allow for early detection of any undesirable effects.
5. Have a plan to undertake post market surveillance by their own.
6. Based on the outcome of PMS analysis of findings, decide appropriate further actions such as feedback into the risk management process, reporting incidents to the authority, making a correction and/or FSCA which should be communicated to users through an Field Safety Notice(FSN).

7. When the PMS is conducted by the authority, fully or partially cover costs related to PMS of medical devices when requested to do so.
8. Establish effective post-market surveillance system that include both active and passive collection of post-market information.

5.4.Importer or wholesaler

1. Coordinate and support the manufacturer on the conduct of medical device PMS activities
2. Liaise PMS related issues between the Authority and the manufacturer
3. Implement recommended actions based on decision of the authority and/or manufacturer
4. When the PMS is conducted by the authority, fully or partially cover costs related to PMS of medical devices when requested to do so.

5.5.Users

The user should:

1. Be vigilant for issues with medical device.
2. As appropriate, document the product name, product code/serial numbers/lot numbers, expiry dates (if any), name of manufacturer, description of issues of affected medical devices
3. Report the above information (2) of affected medical devices to the authority.
4. provide feedback to the manufacturer as soon as they become aware of medical device defect and inform to the authority as the same time.
5. act as instructed when informed about on the use of the medical devices via an FSN.

6. Post-market surveillance mechanisms

PMS is conducted depending upon the information that can be/is to be collected. The objectives of the post-market surveillance should be established based on the activities to be carried out for each specific or group of medical devices. Then, the authority or manufacturer (depend on who is to conduct the PMS) should decide which sources are needed to fulfil these objectives. Based on this, the data should be collected and analysed. Either reactive or proactive post market surveillance may be undertaken based on the purpose and/or available resource.

The manufacturer should establish a system and define mechanisms, as applicable, to undertake both reactive and proactive PMS.

Reactive post-market surveillance, the most basic form of PMS, should be performed by the manufacturers on routine basis. Reactive post-market surveillance is done through collection and evaluation of feedback. All feedback is evaluated to establish the severity of the incident. A root cause investigation might be launched, and further actions undertaken such as correction or corrective action.

Proactive post-market surveillance is the detection of issues through observing users by the manufacturer during trainings, user support, scientific literature, conferences/trade shows and publicly accessible market surveillance information including FSNs, etc.

Manufacturers should collaborate with the authority on proactive PMS which may be conducted to assess the quality, safety and effectiveness of the medical devices placed on the market. The manufacturer should also provide reports of PMS activities undertaken by itself regularly as per the agreed PMS reporting period during marketing authorization, during MA renewal application and/or when requested by the authority.

7. Market surveillance

Market surveillance is a set of activities conducted by the Authority to ensure that medical devices used in the market continue to meet safety, quality and performance requirements.

EFDA and regional regulatory bodies, will collaborate on raising awareness among users and clients/patients about the importance of providing feedback. Regional regulatory bodies should develop a system to receive feedback directly from users and their patients/clients, and to forward it on to the manufacturer. The Authority and regional regulatory bodies may conduct a risk assessment when forwarding feedback to ensure that a registered/authorized medical device is the subject of the feedback. Medical devices that are not registered/authorized would be considered non-compliant and regulatory action may be undertaken. The authority will determine if the concerned medical device is an original one or if it was falsified medical devices with different mechanisms.

The authority and the regional regulatory bodies will conduct market survey with different mechanisms such as comparing with the data base of registered medical devices and/or legally imported medical devices imported via special access/import permit to determine whether the medical device is falsified or illegal.

The Authority will conduct regular market surveillance by proper planning and securing required resources; human and financial. The market surveillance plan will include the type of medical devices to be prioritized using a risk-based approach for closer surveillance. Such preparation will also describe roles and responsibilities, include elements of monitoring and evaluation, timelines for the various activities and a budget.

As part of the market surveillance, the Authority receive and evaluate the investigation reports from manufacturers which should contain a description of any actions taken in relation to a reported incident, including a root cause analysis and analysis of impact on similar products that they manufacture for further review and necessary regulatory actions.

The market surveillance under taken by Authority may be by reviewing relevant gathered data or by establishing a mechanism for the testing of medical devices to ensure that they continue to meet their quality, safety and performance requirements. Such testing may be conducted in its own laboratory or outsourced to an accredited laboratories or laboratory designated by the Authority if the product owner is required to undertake the testing of medical devices.

The authority will notify the final evaluation results of the reviewed manufacturer's investigation report. The major activities performed include:

- Review manufacturer investigation reports
- Decide if regulatory action is required
- Share information with other NRAs
- Forward feedback to manufacturer,
- Conduct risk assessment

EFDA may also under takes testing procedures as part of market surveillance.

8. Methodology

8.1.Determining medical devices to be surveyed

Medical devices to be included in the PMS should be identified by applying risk-based approaches. EFDA uses the feedback and complaints from health institutions, health professionals and patients on the safety and performance of medical devices as one of the basic inputs for conducting post market surveillance. In additions, collaborating with other actors, such as national disease control programmes, may help to identify medical devices.

The following are some of the risk factors to be considered during selection of medical device:

- Extent of population exposure
- Risk level of medical devices
- Manufacturing, technology and distribution chain complexity
- Manufacturer/importer profile and trend analysis report
- Extent of harm due to poor quality or performance
- Availability of the medical device on the market during the survey period
- Device Incident report
- Climatic condition (humidity, temperature, pressure)
- Availability of in use services (maintenance, requalification/verification, calibration etc)

8.2. Selection of survey area

8.2.1. Selection of geographical area

Based on the surveying, sampling and testing plan, risk-based selection should first be applied to the geographical areas where the survey or sampling of medical devices will be conducted. Such criteria could include poor storage conditions, harsh weather conditions, poor access, high disease burden, population size, porous border zone, presence of illicit market, complexity of supply chain, and specific issues reported by prior inspections as well as feedback from users. Such selection criteria should be identified and applied during the initial planning in collaboration with key stakeholders.

8.2.2. Types of data or sample collection sites (data collection/sampling level)

Survey data and/or sample collection should include all levels of formal medical devices supply chain as well as the illegal sources. The following levels should be considered during sample collection:

Level 1: Points of entry to the market: e.g. Private warehouse of Importers/manufacturers, central and district medical stores. Governmental and NGO central stores and hubs or other facilities that supply directly within various programs.

Level II: Regulated retailers: e.g. wholesalers and/or distributors, retail pharmacies

Level III: Health institutions: e.g., hospitals, standalone diagnostic centres and medical laboratories, health centres, sub-health centres, district hospitals, Clinics, health post, temporary diagnostic and treatment centres

Level IV: Illegal supply chain selling medical devices outside the approved distribution system. It includes Informal or unauthorized market (open market, shops and sales of medical devices via the Internet).

Using the risk assessment tool, risk levels are attributed to each level with the highest risk at level IV and lowest at level I.

Survey and sampling should usually be performed in both the public and private sectors as well as in the “informal market”, i.e. both licensed and unlicensed outlets should be included. Types of sites for data and/or sample collection should be selected in the way that will best serve the survey objectives and the selection should be explained in the protocol.

Specific data and/or sample collection outlets may be selected using statistically valid sampling method or purposive sampling based on PMS risk-based screening tool; from the list prepared from each sentinel site before collection starts.

8.2.3. Mapping data and/or sample collection sites/areas

Once the types of data and/or sample collection sites have been selected, the areas or regions to be surveyed and/or sampled need to be mapped and the sites where data or samples will actually be collected during the survey should be identified (by address and facility type). Good local knowledge of the distribution and supply chain structure for the target medical devices and information on where users/ patients obtain devices is needed. Cooperation with relevant disease control programmes, federal and regional public health institutions, regional regulatory bodies and importers of the product in this respect is crucial.

8.3. Determination of data and/or sample collection outlets

A risk-based tool will be used to identify the actual outlets from which the samples of medical device are going to be collected.

The risk based tools enables to implement risk-based approaches to answer important questions for post-marketing surveillance, including:

1. which geographical locations and outlets should be sampled,

2. how many geographical locations and outlets should be sampled, and
3. how many samples should be collected.

8.4. Sampling Designs

Risk-based assessments inform the selection of geographical area and type of medical devices to be surveyed and /or sampled, and they must be similarly applied to select the sampling sites. Distribution of medical products in Ethiopia occurs through public, private, or NGOs; but illegal supply chains should not be overlooked, each of which carry different risks. When developing site selection criteria, necessary considerations include the local knowledge of the supply chain for target products, the availability and accessibility of target medical devices, and information on where the user/patients obtain products or patients get services.

Sampling could be performed using convenience, random, stratified random, or lot quality assurance sampling methods, and may use mystery shoppers/trained data collectors or overt sampling depending on the objectives and convenience of the study.

Because poor-quality, and unsafe medical device are regularly found in hard-to-reach and informal outlets in unregulated sectors, it is important to establish sentinel sites in carefully selected locations that pose the greatest risk to the population.

As applicable for specific medical device, samples collected for laboratory testing should have at least six months or at least three months (for medical device with shelf life of one year) until expiry as this allows sufficient time for testing before the product expires.

8.5. Sampling Plans

Sampling plans should be prepared for each data and /or sample collection area involved in the survey and should be following requirements identified in the survey protocol.

They should specify the:

- ✓ individual sites where collectors should collect data and/or samples (by facility type and address, possibly including global positioning system (GPS) coordinates);
- ✓ name of medical devices to be reviewed or sampled (by package size,);
- ✓ minimum number of devices quantity to be reviewed (as appropriate) or collected per sample;
- ✓ total number of medical devices to be reviewed or number of samples to be collected in the relevant collection area

Sampling plans should also contain detailed instructions for data or sample collectors.

8.5.1. Quantity of medical device to be collected

Use of the risk-based approaches discussed in previous sections reduces the potential number of samples to collect. However, the number of units to collect per sample depends on the objectives of the sampling and testing activity, the type of medical device, the planned tests to be applied, and the approved medical device specification.

The sample of medical device collected should not be taken out of the original primary and secondary packaging, and only intact and unopened packages should be collected.

Sampling plans in the survey protocol usually define the minimum and maximum number of medical devices to be collected per sample. The appropriate number of packages are collected in relation to the available package size and the number of devices units per sample should allow:

- ✓ the planned tests to be conducted;
- ✓ investigation and confirmatory testing of samples if found to be out-of-specification (OOS) as per EFDA's OOS Procedure
- ✓ sufficient retention samples to be used in case of dispute.

8.5.2. Criteria for out lets substitution

In case where the data or sample collectors cannot get samples from the already randomized collection outlets the survey protocol should have a substitution criteria to get the planned number of samples. The following are possible scenarios that may force the survey to have a substitution criteria:

- a. If the randomly selected sampling outlet is closed
- b. If the medical device is not available or the dispenser/seller is not willing to offer in case of mystery shopping
- c. For laboratory testing; if the available medical device in the outlet has less than six months remaining shelf life or three months (for medical device with shelf life of one year)
- d. When the available stock are limited and that medical devices is crucial for life of the user

- e. When there is possibility of not getting minimum quantity of medical devices(for testing) in the collection outlet.

Note: Data/Sample collectors may substitute sampling outlets by replacing the randomly selected sampling outlet by the nearest similar level facility found in the same stratum.

8.5.3. Definition of Sample

The survey protocol should clearly define a sample to ensure uniformity in the collection of data or number of medical devices, based on defined attributes that determine a sample.

8.6. Data or Sample collection

The survey protocol should identify the type of sampling technique to be followed depending on the survey objectives, the regulatory status of the target medical devices and what is known about the knowledge and attitude of the sellers or service providers (i.e. whether they know that the outlet is selling poor-quality medical device, institutions use poor performing device, and understand the health, legal and ethical implications). Samples of medical device is collected as per Medical device sample collection form (Annex 1) of this guideline. Basically, both kinds of sampling techniques; overt and covert, may be used separately or together.

8.6.1. Overt versus Covert sampling

If service providing institution or outlet staff are anxious to avoid poor-quality medical devices and are informed about the survey objectives, overt sampling with feedback would allow more data to be collected on poor-quality and/or poor performing medical devices and their risk factors.

Mystery shopper mainly employed for sample collection. However, the authority may employ external experts to collect data on quality and performance of medical device during the survey. In such case, the protocol should reflect this scenario. In covert sampling the mystery shopper mimics a “normal shopper” from the community in which the outlet is located and should dress, speak and behave appropriately for that community. Shoppers should use a standard scenario, e.g. pretending to be a visitor from another part of the country who needs some medical devices for a specific reason. Mystery shoppers should be prepared to explain the real purpose of their visit to protect themselves if their identity is revealed.

8.6.2. Training (instructing) data and/or sample collectors

Data and/ or sample collectors should be trained or orientated on data collection or sampling procedures and techniques; on how to approach outlets/health institutions; and how to request for medical devices or information. The composition of the data or sample collectors has to be determined in each protocol.

8.7.Storage and transportation of samples or transfer of data

Inappropriate handling, storage, and transportation of samples affect the overall integrity of medical devices and can compromise results. This is particularly true for medical devices that have poor stability profiles and/or require cold chain transportation. It is important to observe the following best practices throughout the chain of custody of the products:

- Avoid excessive mechanical vibration during transportation.
- Store in original container, where available, and label accordingly.
- Store away from sunlight and excessive humidity.
- Label each sample with the location of collection, number of samples collected, name of the sampler and any observation at the time of collection.
- Samples that are light or heat sensitive may require special handling, transportation, and storage conditions. If cold storage is indicated, store in an appropriate container and monitor the temperature during transportation.
- All samples should be packaged adequately and transported in such a way as to avoid breakage and contamination. Any residual space in the container should be filled with a suitable material.

All information gathered regarding surveyed medical devices should be stored in appropriate way to prevent loss of both hard copy and/or soft copy data. All data should be transferred to the center for analysis in the way that ensures their integrity.

Note: Details of sample storage and transportation conditions should be included in the study protocol and the sample collectors should also be trained appropriately.

8.8. Testing

8.8.1. Laboratory Testing

Medical devices quality testing is an important component of post-marketing surveillance system for those medical devices that can be tested. The collected samples should properly deliver to the quality control laboratories as per Annex 2 of this guideline. Laboratories should test the collected products on a timely basis, according to the protocol, to clearly identify its quality, performance/effectiveness and counterfeited products. The collected samples should be tested before they expired. The specific tests to be carried out depend on the products collected and the specific objectives of the study. The test could be in full or selected test parameters as per approved specifications.

If the testing is outsourced to a competent external testing laboratory, within the usual selection procedure and the resulting agreement, the following should be clearly specified in addition to the usual elements of such agreements (such as deadlines and financial arrangements):

- Name of medical devices and numbers of samples to be tested, tests to be conducted and specifications to be used, according to the testing protocol.
- responsibilities of the laboratory during the survey
- declaration of possible conflict of interest and confidentiality agreement made by the laboratory;
- acceptance of a possible audit of the laboratory,
- access to records and retained samples
- Re-test fees in case of out of specification test results
- Custom clearance related issues for samples sent to abroad testing laboratories

8.8.2. Tests to be conducted

Laboratory testing of all collected samples should be performed according to the testing protocol, which is a part of the survey protocol, and should be agreed with the testing laboratory.

If testing is expected to provide a full picture of the quality of target medical devices, it should be tested in accordance with the test parameters and specifications of latest version of respective ISO standard(s) and/or official compendia. The major tests categories may include:

- Visual inspection (eg appearance, package integrity etc);
- Physical tests (e.g. pH, length, thickness)
- Chemical tests (e.g. qualitative or quantitative)
- Mechanical test (e.g. tensile strength, texture)
- Microbiological (e.g. Sterility test)

8.8.3. Test methods and specifications

Test methods and specifications should be selected in the way that will best serve the survey objectives. In general, when samples of the same medical devices from different manufacturers are collected in a survey, they should be tested using the same method and specification to enable comparison of samples from different manufacturers. This specification is then used to decide on compliance or non-compliance of tested samples for the purposes of the survey. For each of the target medical devices the protocol should contain the list of tests to be conducted, reference to methods to be used and specifications to be employed.

8.8.4. Registration status of the sample

Registration status of the collected samples will be reviewed using the eRIS database of registered products by comparing the label of the collected products with the original label provided from the product manufacturer at the time of registration. Evaluation of the product label against the standard label may not be relevant for products that are not registered by authority.

9. Data analysis, communication and action

9.1. Data analysis

To allow proper interpretation, the data obtained during collection and testing of samples should be summarized and appropriately organized linking each sample with all the data gathered and ensuring consistency and security. Suitable precautions should be taken to avoid errors. For analysis of large sets of data, statistical software may be used.

After all the assessments, the PMS task force should prepare a standard report based on the findings. Every post-market surveillance report should contain a summary of the results and

recommendations that help the authority to decide on. Finally, the report should be officially submitted to responsible body for review and any relevant measures.

9.2. Communication

The findings of the post marketing surveillance including measure taken must be communicated to the relevant stakeholders and the public. Different mechanism can be used to disseminate/communicate the PMS findings results. These are:

- Present results in different forums to raise awareness on safety, quality and performance of medical devices
- Publish in different bulletins, press release newsletters, magazines and other relevant printed materials
- Using different electronic medias including radios and TVs
- Uploading on the authorities website and other recognized websites

9.3. Action

Depending on the data presented from the survey and the potential public health importance of the findings, the authority may take a variety of actions, including but not limited to:

- further testing of samples and requesting additional information or clarification from market authorization holders.
- Recall of products according to the EFDA's recall directive, guideline and SOP. Manufacturers and importers have the responsibility to conduct the recall process.
- Decommissioning or disposal of illegal medical devices
- Suspension of a product's marketing authorization
- Warning letter sent out to manufacturer and/or importer of the specific medical devices
- Adequate and proportional sanctions, penalties and prosecution upon conviction for violations of the applicable legislation.
- communicate with relevant stakeholders like regional health bureaus, neighboring countries and other relevant organizations
- Any relevant legal actions in accordance with the administrative measures & complaint handling guideline and other national laws

Reference

1. Food and Medicine Administration Proclamation (Proclamation No. 1112/2019), 2019
2. Guidance on Post marketing Surveillance and market surveillance of medical device including invitro diagnostics, World Health Organization, 2020.
3. Guideline for post market surveillance of in vitro diagnostics, Version 5, World Health Organization, 2015.
4. Guidance for Implementing Risk Based Post marketing Quality Surveillance in low-and Middle-income Countries, Promoting the quality of Medicine (PQM), USP and USAID, 2018.

Annex 1: Sample Collection Form for Medical Devices

| | | |
|---|--|---|
|  | Medical Device Sample Collection Form |  |
| Title: | | |
| Name of sample collection site: | | |
| Address of sample collection site: | Region:- _____ Tel:- _____ | Zone:- _____ City/Woreda:- _____ |
| Sample Code :-First two letter of the name of product/sampling date, DD-MM-YY)/sequence number | | |
| Product detail | | |
| Product name | | |
| Expiry date(s): | | |
| Manufacturer name | | |
| Country of Origin: | | |
| Product code/catalogue number(s): | | |
| Lot number/batch number/serial number(s): | | |
| Associated devices/accessories (lot numbers/expiry dates): | | |
| Instructions for use version number: | | |
| Software version number: | | |
| UDI-DI/UDI-PI: | | |
| <p>Note: Sample collected must remain in their original container, intact and un opened. A sample having remaining expiry date of less than six month and 3 months (for devices with less than one year shelf life) must not be collected.</p> | | |

Annex 2: Sample Submission Form for Laboratory Analysis

Data of sample collectors

| | |
|-------------------------|--|
| Prepared by: | |
| Inspectors name: | |
| Institution: | |
| Telephone: | |
| E-mail: | |
| Year: | |

Details of Sample Collection and Results

| Serial No. | Sample Code No. | Province or Region (within country) | Origin of Sample | | | | Medical device Name | Name of Manufacturer | Manufacturer Addresses | Date Sample was Collected | Batch or Lot Number | Expiry Date | Is the MD registered | Conclusion |
|------------|-----------------|-------------------------------------|------------------|----------------------|--------------------|------------------|---------------------|----------------------|------------------------|---------------------------|---------------------|-------------|----------------------|------------|
| | | | Facility Name | Location of Facility | Sector of Facility | Type of Facility | | | | | | | | |
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