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Guidance on Post-Market Surveillance of In-vitro Diagnostic Medical Device (IVDMD)

Draft for Public Comment

Central Drugs Standard Control Organization
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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

(In-Vitro Diagnostic Division)

Guidance Document

Title : Guidance on Post-Market Surveillance of In-vitro Diagnostic Medical Device (IVDMD)

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Notice:

This Guidance document is aimed only for creating public awareness about In-Vitro Diagnostic Devices Regulation by CDSCO and is not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Medical Device Rules, 2017 and subsequent amendments and clarifications issued by CDSCO time to time for all their professional needs.

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1. INTRODUCTION

In-vitro Diagnostics (IVD) tests are conducted outside the body of the patient, in a laboratory set-up to screen, diagnoses or monitor diseases and infections.

In-vitro Diagnostics medical devices are regulated under the Medical Devices Rules, 2017 notified by The Ministry of Health and Family Welfare, Government of India under the provisions of the Drugs and Cosmetics Act, 1940.

These Rules came into force effective 1st January, 2018 to regulate the manufacture, import, sale and distribution of notified medical devices and In-vitro diagnostics (IVD) medical devices in the country.

The proposed Guidelines on the Post-Market Surveillance for IVDs have been prepared to facilitate and strengthen the reporting of Adverse Events attributable to in-vitro diagnostic medical devices in India and to facilitate access to safe, appropriate and affordable in vitro diagnostics (IVDs) of good quality in an equitable manner.

2. PURPOSE

The purpose of post-market surveillance is to protect individual health and public health through continued surveillance of IVDs once they are placed on the market by reducing any risks. Such activities should ensure the manufacturer's obligations are fulfilled through ensuring they are aware of event which enables them to undertake and assessment of any risks, and as appropriate any suggested steps to risk mitigation.

This is to be achieved through evaluation of reported incidents and where appropriate, dissemination of information, which could be used to prevent such repetitions or to alleviate the consequences of such incidents.

This document provides guidance on the requirements of reporting of Adverse Events for the following IVD's.

a) IVD's falling under Class C and Class D as per the risk based classification provided under Medical Device Rules, 2017.

Examples: IVD's for the detection of HIV, Hepatitis, Syphilis, Malaria, Dengue, TORCH infections, Cancer markers, Cardiac Markers etc.

b) Point of Care Test (POCTs) or Home-Use IVD medical devices.

Example: Glucometer and strips.

Note: Class B IVD medical devices have not been included under these Guidelines since Intended use of these diagnostics medical devices is to provide preliminary test results which require further confirmation by supplemental or confirmatory tests. The IVD medical devices falling under this class are not the sole determinants of any diagnosis.

Vigilance reporting for IVD medical devices

Vigilance reporting may be more difficult for medical devices like IVDs which do not generally come into contact with patients.

It can sometimes be difficult to demonstrate direct harm to patients in case of IVDs owing to their intended use, unless the device itself causes deterioration in state of health.

Harm to patients attributable to IVDs, is more likely to be indirect.

Manufacturer, importer, distributor or user of an IVD medical device, will need to identify event/s as under and notify to the regulatory authority:

a. That has or could result in indirect harm to the patient.

b. That has led to or resulted in death or serious deterioration in state of health of the patient.

3. SCOPE

This document is applicable to all persons who manufacture, import, distribute or use IVD medical devices in India.

4. DEFINITIONS

Definitions that do not indicate they are set out in the Regulations are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

Post-market surveillance: "Post Marketing Surveillance" means systematic process to collect and analyse information gained from medical device that have been placed in the market;The purpose of post-market surveillance is to protect individual health and public health through continued surveillance of IVDs once they

are placed on the market by reducing any risks. Such activities should ensure the manufacturer's obligations are fulfilled through ensuring they are aware of event which enables them to undertake and assessment of any risks, and as appropriate any suggested steps to risk mitigation.

Serious adverse event: "serious adverse event" means an untoward medical occurrence that leads to,—

(i) a death; or

(ii) a serious deterioration in the health of the subject that either-

(A) resulted in a life-threatening illness or injury; or

(B) resulted in a permanent impairment of a body structure or a body function; or

(C) required in-patient hospitalisation or prolongation of existing hospitalization; or

(D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or

(iii) foetal distress, foetal death or a congenital abnormality or birth defect;

Adverse effect: means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or is likely to have, on the body or health of humans, when such a medical device is used by or administered to humans.

Adverse events: any event or other occurrence that reveals any defect in a medical device or concerns any adverse effect arising out of the use thereof.

Abnormal use: Act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer.

Harm: physical injury or damage to the health of people or damage to property or the environment.

Immediately: For purpose of these guidelines, immediately means without any delay that could not be justified.

Incident: any malfunction or deterioration in the characteristics and/or performance of a device, as well as inadequacy in the labelling or instruction for use, which directly or indirectly, may lead to or might have led to the death of the patient or user or to a serious deterioration in their state of health.

Indirect harm: in the majority of cases, IVD medical devices, due to their intended use, do not directly lead to physical injury or damage to the health of people. These devices therefore are more likely to lead to indirect harm rather than direct harm.

Harm may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device.
Examples of indirect harm include:

- Misdiagnosis
- Delayed diagnosis
- Delayed treatment
- Inappropriate treatment
- Absence of treatment
- Transfusion of inappropriate material

Indirect harm may be caused by:

- Imprecise results
- Inadequate quality controls
- Inadequate calibrations
- False positives or
- False negative results.

Intended purpose: the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instruction for use and/or in the promotional material.

Intended use: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Note: Aspects that are considered in the intended use include

- what is detected
- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);
- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
- whether it is automated or not; whether it is qualitative or quantitative;

- the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine);
- testing population ;
- the intended user (e.g. lay person, highly trained laboratory professional, minimally trained health care worker, self-testing);
- the intended setting of use (e.g. point of care, reference or diagnostic laboratory setting, primary health care setting)

User error: an act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

User: the health care institution, professional, patient using or maintaining medical devices.

Point-of-Care/ Home Use tests: Point of Care tests are simple, in vitro Diagnostics medical devices that can be performed at the bedside in a hospital setting, at the physician's chamber or at home by the patient.

Examples include: Glucometer with strips for the estimation of glucose levels in the blood, rapid coagulation tests (PT/INR) , rapid cardiac marker tests, drugs of abuse screening tests, urine strip tests, pregnancy test, fecal occult blood test, food pathogens screening test, hemoglobin test, infectious disease tests and cholesterol screening test amongst others.

Qualitative tests: qualitative tests are tests that provide information that can not actually be measured. They provide information in the form of 'yes' (positive) or 'no' (negative) results.
e.g. ELISA and rapid card tests for HIV, HCV, HBsAg, Malaria, Dengue etc.

Quantitative tests: quantitative tests provide information about quantities; that is, information that can be measured in numbers.
e.g.: End point or kinetic biochemistry tests, Complete Blood Count etc.

In vitro diagnostic (IVD) : A 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. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Clinical sensitivity: The number of true positive specimens identified by a given assay as positive divided by the number of specimens identified by the reference assays as positive, expressed as a percentage.

$$\text{Specificity (\%)} = \frac{\text{True Positives}}{\text{True Positives + False Negatives}} \text{ X } 100$$

Clinical specificity: The number of true negative specimens identified by a given assay as negative, divided by the number of specimens identified by the reference assays as negative, expressed as a percentage.

$$\text{Specificity (\%)} = \frac{\text{True Negatives}}{\text{True Negatives + False Positives}} \text{ X } 100$$

Component: Any raw material, substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device.

Complaint: Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a IVDs after it is placed on the market.

Field safety corrective action (FSCA): 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): A communication sent out by the manufacturer or its representative to the device users in relation to a field safety corrective action.

Vigilance: One of the post-market activities undertaken by the manufacturer to protect the health and safety of patients, which relates to monitoring of adverse events (according to the definition of an adverse event given above), investigation of adverse events to determine root causes and the consequent corrective and preventive action.

Recall: "recall" means any action taken by its manufacturer or authorised agent or supplier to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device (IVDs),—
(a) is hazardous to health; or
(b) fails to conform to any claim made by its manufacturer relating to its quality, safety or efficacy; or

(c) does not meet the requirements of the Act and rules;

Recalls are an effective method for removing or correcting marketed products, their labeling, and/or promotional literature. Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or judicial actions, especially when the product has been widely distributed. Licensee's (Importer/Manufacturer) may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall, in response to a formal ordered issued by concern licensing authority (CLA/SLA).

Periodic Safety Update Reports (PSURs): PSURs mean (i) Subsequent to approval of an New In vitro diagnostic, it shall be closely monitored for their clinical Safety and performance once they are marketed. The applicants shall furnish Periodic Safety Update Reports (PSURs) in order
to,-

(a) Report all the relevant new information from appropriate sources;
(b) Relate these data to patient exposure;
(c) Summarise the market authorisation status in different countries and any significant variations related to safety, performance; and
(d) Indicate whether changes will be made to product information in order to optimize the use of the product.

5. BASIC PRINCIPLES

A. RATIONALE FOR POST-MARKET SURVEILLANCE:

a) Pre-market assessment as a basis:

A degree of pre-market assessment of IVDs is recommended for any product prior to entry into the marketplace in each country of intended use. While pre-market assessment of IVDs can provide information on a product's safety, quality and performance, there might be questions that cannot be answered in the pre-market stage or issue that may arise after the product is marketed.

b) Post-market surveillance to protect public health:

The safety, quality and performance of IVDs should be further verified upon delivery and before distribution to laboratories and other testing sites. Post-market information on IVDs empowers NRAs to detect, investigate, communicate and contain events that threaten public health security and to take appropriate action.

B. POST MARKET SURVEILLANCE MECHANISMS:

Post-market surveillance can be divided into reactive and proactive measures,

a) Reactive Post-market surveillance:

Information on quality, safety or performance of an IVD on the market is collected reactively through notification by users and evaluation by manufacturers of complaints, including adverse events. The reactive nature of this statement refers to the fact that the problem has already occurred, and may have affected a clinical decision

b) Proactive Post-market surveillance:

Additional information on quality, safety or performance may also be collected proactively through lot verification testing. This relates to proactively trying to identify a problem before it affects a clinical decision. Lot verification testing is conducted after shipment to the buyer (countries) and can be performed both pre-distribution and post-distribution to end users.

Manufacturers should also collect post-market surveillance through actively gathering evidence from the literature on their product or similar products, through seeking feedback from customers, and post-market clinical follow up.

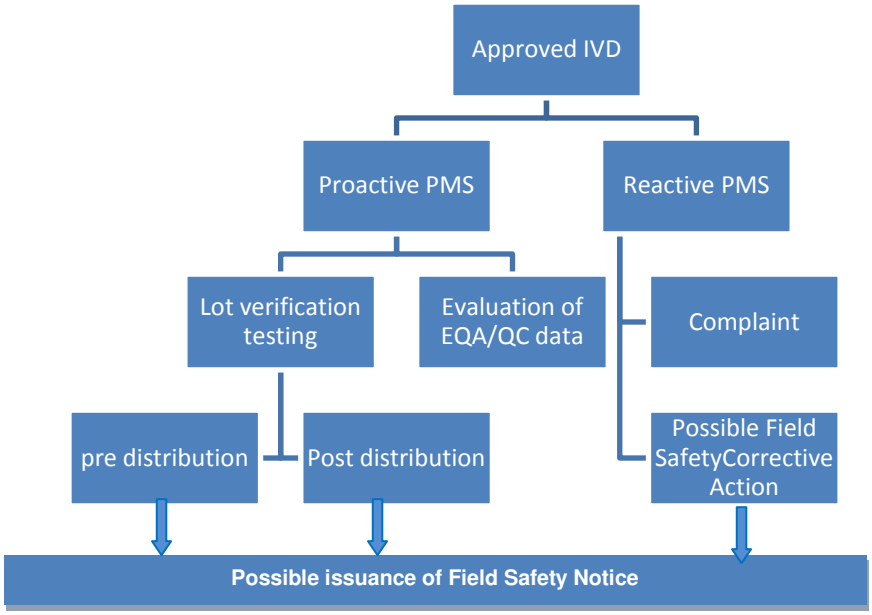

FIGURE 1- STEPS FOR POST-MARKET SURVEILLANCES

6. STAKEHOLDERS' ROLES IN POST-MARKET SURVEILLANCE FOR IVDS

The decision to implement post-market surveillance should involve all relevant stakeholders. End users (as well as procurers and implementers), manufacturers, and testing laboratories) and concern licensing authority should be involved in the decision to expand national regulatory function to post-market surveillance of IVDs.Table1 gives an summary of the roles of different stakeholders in post-market surveillance of IVDs.

Table 1

Stakeholder Activity Details	Stakeholder Activity Details	Stakeholder Activity Details
I. End users / procurers	1. Identify problems 2. Document problems 3. Report complaints 4.Cooperate in sample verification testing	• End users should document any problems, and report complaints (Including adverse events) to the manufacturer, the relevant licensing authority CDSCO/SLA, Mvpl •Trained and qualified personnel are responsible for sampling of test kits for post-distribution lot verification testing. •Procurers (specialized procurement agencies or implementing agencies)

		should contribute to these activities on behalf of end users and in accordance with quality assurance policies that govern their procurement and distribution of IVDs.
II. Manufacturers/ Importers	1. Classify complaints 2. Undertake root cause analysis 3. Take corrective action	• Manufacturers should implement an effective post-market surveillance system with both active and passive collection of post-market information, including complaints. • Manufacturers must establish a documented procedure for a feedback system to provide early warning of quality problems and for input into corrective action/preventive action processes (as required by the ISO 13485 standard / MDR 2017).
III. Licensing authorizes CDSCO /SLA	1. Collect reports of complaints 2. Oversee lot verification testing 3. Collect other post-market Information. 4.Site inspecting/investigation (if required) 5. Take regulatory action	• Licensing authority (CLA/SLA) should conduct pre-market assessment and active rather than passive post-market surveillance for products on sale within their market. • Regulatory controls should be phased in depending on available regulatory capacity and resources, and using a risk-based approach.
IV. Testing laboratories	1. Receive and store samples of test kits 2. Prepare and maintain lot verification testing panels 3. Conduct testing and record data 4. Analyze data and report a result to Licensing authorizes (CLA/SLA).	• Testing laboratories should conduct lot verification testing in coordination with Licensing authority (CLA/SLA) where ever applicable.

PART I: END USERS / PROCURERS

OVERVIEW OF RESPONSIBILITIES

End User: The end user may be "the operator (meaning the individual performing the IVD; this individual canbe a laboratory worker, a healthcare provider or a lay person with minimal training;) or the healthcare provider (meaning the individual ordering, receiving or acting upon the examination results on behalf of a patient; this individual can be a physician, nurse, ambulance attendant or any other person) making a medical decision based upon IVD examination results.

Appropriate use of IVDs: End users should handle and use IVDs according to manufacturer's instructions for use to maintain their quality, safety and performance.

Quality management system: The principles for quality systems in medical laboratories are laid down in ISO 15189 Medical laboratories — Particular requirements for quality and competence and include: organization, personnel, equipment, purchasing and inventory, process control (quality control), information management, documents and records (standard operating procedures, standardized worksheets, reports), occurrence management, assessment (external quality assessment schemes and supervision), process improvement, customer service, and facilities and safety.

Storage: Users must ensure proper storage of the test kits according to the manufacturers' instructions for use (either at climate-controlled room temperature or in a refrigerator), and should monitor the temperature of the storage facility.

COMPLAINT REPORTING:

The end users should notify the manufacturer of all complaints related to the use of their product. Furthermore, the relevant NRA should be notified of any serious, moderate or change in the trend of mild adverse event related to IVD. These classifications will be described later in this guidance. In any case where the manufacturer is not aware of a complaint, the relevant NRA should ensure they are informed. Complaint reporting is a reactive post-market surveillance measure. It covers activities undertaken after any party becomes aware of adverse events, malfunctions, results of testing or other relevant information about an IVD placed on the market. It is based on a cooperative and effective exchange of information between all the parties.

Verify complaints: In case of perceived complaints, the end user (in conjunction with appropriate technical expertise) should document the complaint fully by

determining all aspects (lot number, expiry date, storage temperatures, etc.) and possible causes such as product quality, safety or performance, use error and abnormal use.

1. IDENTIFY COMPLAINTS:

Types of complaints: Complaints may include-

- **Administrative/contractual** complaints related to any aspect of the procurement contact not fulfilled e.g. agreed delivery time not adhered to, agreed guaranteed shelf life upon delivery not adhered to, incorrect product and/or quantity delivered, etc.
- **Technical complaint**, affecting the safety, quality or performance of an IVD, for example:

Malfunction or deterioration in the characteristics or performance, inadequate design or manufacture; inaccuracy in the labelling, inappropriate instructions for use and/or promotional materials, or any other issues might be reported that result in a significant public health concern. Information about such issues may become available in other ways than through reporting (for example through literature and other scientific documentation).

Adverse events (Incidents): Some technical complaints may lead to an adverse event. Adverse events (also called incidents) are consequences of problems with IVDs that may lead to death or serious deterioration in health of a patient, user or other person. As an IVD is not directly used on an individual, the harm is indirect “a result of an action taken or not taken on the basis of an incorrect result obtained with an IVD”.
Notification and evaluation of adverse events is also known as vigilance.

What should be reported?

Adverse events should be reported in any of the following circumstances:

1. When an incident leads to death of a patient, user or other person.
2. When an incident leads to serious deterioration in health of a patient, user or other person (also known as serious injury).
3. No death or serious deterioration in health occurs but the event might lead to death or serious deterioration in health.
4. When an incident might happen as a consequence of a medical decision or action taken or not taken on the basis of results given by the IVD, typically:
   - Misdiagnosis:
   - Delayed diagnosis;
   - Delayed treatment;
   - Inappropriate treatment;
   - Transfusion of inappropriate (contaminated) materials including blood products, tissues or organs

5. Use errors:

that did result in death or serious deterioration in health or that have a negative trend with the potential for death or serious deterioration in state of health or public threat.

Adverse events may come as a result of the below:

- A malfunction or deterioration in the characteristics or performance;
- An incorrect or out-of-specification test result (e.g. a false positive or a false negative test result that results in incorrect status given to individual);
- An inaccuracy in the labelling, instructions for use and/or promotional materials;
- Discovery of a serious public health threat;
- Use error;
- Any other information that becomes available.

Identifying incorrect test results:

For IVDs used in a one-assay testing strategy (e.g.malaria IVDs), it may be easier to determine false positive and false negative rates.

For IVDs used in a multi-assay testing strategies (i.e.HIV IVDs), it may be difficult to attribute misdiagnosis of the HIV status to one assay over another. False results might be caused by cross reactivity between test kits, which is not a product defect. Information on the testing algorithm must be captured to understand the specificity and/or sensitivity attributes of a given test kit.

This is particularly important for a test kit that may be used interchangeably as a first line assay in one country but as a second or third line assay in another country.

Impact of incorrect test results:

False positive HIV results may be less likely have an impact on people's health and survival than false negative HIV results. However, the psychological impact of a false positive HIV test result can be enormous. Commencing an individual on treatment when they are not indeed positive for an infection may increase the risk of drug toxicity, resistance, and in any case administering medication and perhaps ordering additional testing is a waste of resources (both financial and otherwise).

False positive malaria results may cause the operator to assume malaria as the cause of clinical signs and symptoms and mask another cause of febrile illness that may be life-threatening. False negative malaria results will likely lead to withholding a prescription of anti-malarial drugs and hence may have a life-threatening consequence.

Inadequate manufacturer instructions:

In the case of potential errors by users, labelling and instructions for use should be carefully reviewed for any possible inadequacy. Inadequacies in the information supplied by the manufacturer that led or could have led to harm to users, patients or third parties should be reported by the manufacturer to the NRA.

2. DOCUMENT COMPLAINTS

Users should document any problems with IVDs using information taken from the testing/laboratory logbook and inventory records including affected product code(s), affected lot number(s),and expiry date(s), affected consignments or test kits, affected users, and any measures taken.

Photographs of affected test devices and/or test kits should be taken to illustrate the problem.

Users should keep and appropriately store at least 1-2 affected test kits (up to 60 tests) as retention kits for later testing, if required.

3. REPORT VERIFIED COMPLAINTS

All verified complaints should be reported by the end user to the manufacturer as soon as possible, In addition, any complaints that are as serious, moderate or a change in trend of mild adverse events may be reported to the authorities, as soon as possible.

PART II: MANUFACTURER / IMPORTER

OVERVIEW OF RESPONSIBILITIES:

Knowledge of relevant standards:

Manufacturers of IVDs should be familiar with applicable standards including Fifth Schedule of MDR 2017- Quality Management System for medical devices and in vitro diagnostic medical devices , Quality management systems - Requirements, ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes and ISO 14971:2007 Medical devices - Application of risk management, which outline their requirements for compliance with post-market surveillance aspects of these standards.

This part describes the manufacturer's / Importer's post-market surveillance obligations, and gives details on root cause analysis of reported adverse events and field safety corrective action to address them.

Manufacturers must verify each lot pre-shipment:

Manufacturers are obliged to perform quality control lot release as part of the requirements of Fifth Schedule of MDR 2017 which states that there must be adequate monitoring and measurement of product and evidence of conformity with an agreed acceptance criteria. Where manufacturers purchase key components for the product, these components must be verified to ensure they meet specified purchasing requirements. Furthermore, there must be a process to identify and control product that does not conform to requirements and to prevent its unintended use or delivery.

Responsible person:

To ensure an efficient post-market surveillance system, manufacturers / Importers of IVDs should appoint a responsible person for post-market surveillance who shall collect and evaluate post-market surveillance information and coordinate all measures related to adverse events. This person should be in charge of post-market surveillance information exchange with end users, respective Licensing authorities.

Complaint handling and vigilance:

The manufacturer / Importer shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained. If investigation determines that the activities outside the manufacturer's organisation contributed to the customer complaint, relevant information shall be exchanged between the organisations involved. If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the compliant handling process shall be documented. Manufacturer shall notify the adverse event to the regulatory authority (CLA/SLA) and establish documented procedures for the same.

All types of reports related to complaints (including adverse events) should be maintained by the manufacturer including: initial/follow-up/final manufacturer investigation reports, root cause analysis reports, corrective action/prevention action plans, any Field Safety Corrective Action and Field Safety Notices, and annual post-market surveillance summary reports. Vigilance information exchange with regulatory authority (CLA/SLA) should be maintained.

Field safety corrective action (FSCA):

Manufacturers / Importers should have in place procedures to facilitate FSCA, including designated personnel, and to maintain records to facilitate traceability for lots of IVDs distributed to users.

Reporting timelines for complaints:

1. Any serious adverse event Initial reports should be reported within 5 working days of becoming aware of an event. Subsequent followup, Causality assessment report and future preventive or corrective steps Within 30

calendar days of becoming aware of an event by the manufacturer /Importer to the concern licensing authority (CLA/SLA).

2. Any moderate adverse event or any change in the trend of mild adverse events should be reported by the manufacturer /Importer to the concern licensing authority (CLA/SLA) within 30 days.
3. All complaints (both administrative and technical including serious, moderate and mild adverse events) must be reported by the manufacturer /Importer annually to the to the concern licensing authority (CLA/SLA) as a periodic summary report.

1. **CLASSIFY COMPLAINTS:**

A method of classification should be used identify the quality, safety and performance issues that pose a high risk to individual health and to public health, and therefore require the most immediate action to protect public health and safety.

As soon as it is received, any complaint must be classified by the manufacturer / Importer as part of the risk management file for the product on risk management for IVDs. The degree of risk will determine the timeline for action, and who should be informed. The requirement for root cause analysis will remain, irrespective of the classification.

Note: not every complaint may need to be considered as an adverse event, and not every adverse event or potential adverse event may lead to a field safety corrective action.

Table 2: Examples of adverse event classifications (this is not a list of exhaustive examples):

Classification	Description	Examples
Serious adverse event	➢ Death of patient, user or other person ➢ Serious injury of patient, user or other person ➢ Death or serious injury of patient, user or other person did not occur but might have ➢ Any false negative result	➢ One or more individuals receive HIV-contaminated blood product that has been produced from one blood donation that was screened as HIV negative by an HIV-1/2 RDT. ➢ An individual presenting for ART initiation has testing repeated to confirm their HIV diagnosis. The re-testing results are negative.
Moderate adverse event	➢ Any false positive result (that resulted in misdiagnosis) • Higher than expected rate of anomalies that lead to invalid, ➢ unreturnable or inconclusive	➢ Invalid rate exceeds 5%. ➢ High background for rapid diagnostic tests. ➢ Greater than expected discrepant rate between assay 1 and assay 2 within a

	results	testing algorithm.
Mild adverse event	➢ Deficiency found by the user prior to use ➢ Adverse event caused by patient conditions ➢ Adverse event caused by device exceeding its service life or shelf life ➢ Malfunction protection operated correctly ➢ Negligible likelihood of occurrence of death or serious injury ➢ Unexpected and foreseeable side effects ➢ Adverse events that might be described by the manufacturer in FSN	➢ Control line does not appear. ➢ Higher than usual background, may or may not obscure reading window and prevent reading. ➢ Desiccant has changed colour. ➢ A component labelled lyophilized is found to be fluid, this is discovered by the user prior to use. ➢ The packaging of a device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, ➢ obvious damage to the packaging was observed, and the device was not used.

2. UNDERTAKE ROOT CAUSE ANALYSIS:

For each complaint received, the manufacturer should undertake a root cause analysis to determine if the complaint (including adverse events) can be verified and root cause can be established. Root cause analysis is a systematic approach to investigating why and how a problem took place, in order to prevent its reoccurrence. There are a number of tools that may be used such as a fishbone diagram.

3. TAKE CORRECTIVE ACTION:

In certain circumstances, corrective action may take place before the root cause can be definitively identified, in order to protect individual health and public health.

3.1 GENERAL PRINCIPLES:

Following the investigation of the complaint, the manufacturer should consider the following possibilities:

- ✓ No action;
- ✓ Immediate correction;
- ✓ Additional surveillance of the IVD in use;
- ✓ Design modification, manufacturing process modification, etc.;
- ✓ Field safety corrective action, including recall or quarantine of existing stock, modification instructions for use or product labeling;
- ✓ Field safety advisory notice issuance, including urgent information to inform those responsible for the device, or affected by the problem;
- ✓ Retraining;

- ✓ Other possible action, such as retesting of individuals and/or special monitoring of individuals previously tested using the affected IVD.

Corrective and preventive action (CAPA):

Based on the results of root cause analysis, corrective and/or preventive action should be taken, where necessary. Corrective action/preventive action (CAPA) is improvements made to the manufacturing process as part of the overall quality management system to eliminate causes of nonconformities. Any process for CAPA should focus on the systematic investigation of discrepancies (failures and/or deviations) in an attempt to prevent their reoccurrence. To ensure that corrective and preventive actions are effective, the systematic investigation of the failure incidence is pivotal in identifying the corrective and preventive action undertaken. The degree of action taken should be dependent upon and related to the risk, size and nature of the problem and its effect(s) on product quality.

Corrective action:

The manufacturer / Importer shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for:-

(a) Reviewing nonconformities (including customer complaints);
(b) Determining the causes of nonconformities;
(c) Evaluating the need for action to ensure that nonconformities do not recur;
(d) Determining and implementing action needed, including, if appropriate, updating documentation;
(e) Recording of the results of any investigation and of action taken; and
(f) Reviewing the corrective action taken and its effectiveness.

Preventive action:

Preventive action is a proactive process undertaken by the manufacturer to identify opportunities for improvement of the IVD in advance, before a problem is identified. Preventive action is taken when a potential nonconformity is identified as the result of lot testing, complaints from the Corrective and preventive action (CAPA)field and other relevant sources of information. Examples of preventive action include (but are not limited to):

- ➢ Reviews of contracts (with key suppliers), purchasing, processes, design;
- ➢ Software validation and verification for analyzers;
- ➢ Supplier surveillance;
- ➢ Preventive maintenance and calibration controls for analyzers;
- ➢ Management review of quality management system;
- ➢ User training programmes, job aids;
- ➢ Trend analysis;
- ➢ Benchmarking.

The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for

(a) Determining potential nonconformities and their causes,
(b) Evaluating the need for action to prevent occurrence of nonconformities,
(c) Determining and implementing action needed,
(d) Recording of the results of any investigations and of action taken, and
(e) Reviewing preventive action taken and its effectiveness.

3.2 FIELD SAFETY CORRECTIVE ACTION:

A field safety corrective action (FSCA) is an 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.

What can cause FSCA:

A FSCA is triggered by information about any problem with an already distributed IVD that poses an unacceptable increased risk when that IVD is used. Such problems include malfunction or deterioration affecting the performance or operational characteristics of an IVD, as well as any inadequacy in the instructions for use which might lead or might have led to the death of a patient, user or other individual or to a serious deterioration in his/her state of health.

Such information may arise from any aspect of post-market surveillance: pre-distribution or post-distribution lot testing, report from the field, review of IVD design, changes in production or component specifications, etc.

Communicating FSCA:

A FSCA is communicated through a Field Safety Notice (FSN);

Reporting FSCA:

The manufacturer / Importer is required to report any FSCA related to a IVD to the concern licensing authorities CLA/SLA.

The FSCA report should include the following information:

- Name and address of the manufacturer / importer;
- Product name, product code and lot number of the affected IVD:
  in the case that the FSCA related to certain lots only, an explanation why the other lots are not affected;
- List of all affected countries (in case of Imported IVDs) ;
- Background information and reason for the FSCA:
  include a description of the IVD deficiency or malfunction, clarification of the potential hazard associated with the continued use of the IVD and the associated risk for the patient, user or other person and any possible risks to patients associated with previous use of affected IVD;
- Relevant parts from the risk analysis;
- Description and justification of the corrective and/or preventive action;

- Advice on the actions to be taken by the distributor and the user (include as appropriate):
    - Identifying and quarantining the IVD;
    - Method of recovery, disposal or modification of the IVD;
    - Recommended patient follow up;
    - A request to pass any attached Field Safety Notice to all those who need to be aware of it.

If the FSCA includes return of affected stock to the manufacturer / Importer or an update of the instructions for use or a modification/update of existing IVDs on- or off-site, records of completed actions should be fully reconciled against distribution records in order to maintain control of the progress of the FSCA.

The final report should contain the following information:

• The final outcome of the reconciliation of the FSCA;

• Root cause of the problem, if known, and proposed action to reduce the chance of recurrence

e.g. redesign, update in the field, improved instructions for use, etc.

3.3 FIELD SAFETY NOTICE (FSN):

Field Safety Notices are an important means of communicating FSCA and related safety information to users. They may also be used to provide updated information about how an IVD should be used.

Distribution of FSN:

Manufacturers / Imorter should inform affected users of any FSCA via FSN. The manufacturer should ensure that the FSN is distributed to all affected users, and must keep track of confirmation of receipt of the FSN. A full, detailed distribution list with contact name and email address for each intended recipient must be kept and must be made available on request.

Affected users are will usually receive the FSN via their procurement agents or through distributors who are obligated to inform all users within their region of supply. Distributors may need to translate the FSN from English or other common language to local language but this needs to be managed to ensure that the translation is of good quality and interprets the message of the FSN correctly.

Content and format:

The manufacturer / Importer should use a standardized format for a FSN. The FSN should be written on company letter head and in English. It may be translated into the regional language(s) of the local area by distributors.

The FSN should include the following items:

- A clear title like “Urgent Field Safety Notice” on the notice itself, the envelope if sent by mail and the subject line if sent by email or fax;

- The intended audience: clear statement about the intended recipient of the notice;
- Concise description of product, product code, lot number;
- A factual statement explaining the reasons for the Field Safety Corrective Action, including description of the problem;
- A clear description of the hazards associated with the specific failure of the device and, where appropriate, the likelihood of occurrence, being mindful of the intended audience;
- The recommended action(s) to be taken by the recipient of the Field Safety Notice including any action(s) recommended for people that have previously used or been treated by affected diagnostics, including recalls;
- Where appropriate, include timeframes by which the action(s) should be taken by the manufacturer and user;
- Designated contact point for the recipient of the Field Safety Notice to obtain further information.

PART III: REGULATORY AUTHORITIES (CLA/SLA):

Concern Licensing authority (CLA/SLA) as a regulatory authority should conduct pre-market assessment and active rather than passive post-market surveillance for products on sale within their market. The NRA should designate a NRL or other recognized laboratory that is assigned the overall responsibility for pre market and complaint verification testing.

Full and complete post-market surveillance for all products is not feasible with available regulatory capacity and resources. Therefore, concern licensing authorities are encouraged to adopt a risk-based approach to both pre-market assessment and post-market surveillance of IVDs placed on their market according to a set of risk classification rules. The level of regulatory scrutiny will depend on the risk the IVD presents and the setting of its intended use.

Depending on the seriousness of the IVD's deficiency discovered in the post-market phase and/or potential for future harm, concern licensing authority (CLA/SLA) may consider the following possibilities:

- ✓ No action;
- ✓ Perform additional in use surveillance of the IVD concerned;
- ✓ Issue an alert giving advice to end users through Public Notice;
- ✓ Require the manufacturer to make appropriate changes in the design, manufacturing process or information supplied with the product;
- ✓ Mandate a product recall/withdrawal;
- ✓ Send the data acquired to the manufacturer to help identify trends that require action.
- ✓ Cancel or suspension of the product license

PART IV: TESTING LABORATORIES:

Concern licensing authority (CLA/SLA) as a regulatory authority should designate a testing laboratory for pre market and complaint verification testing of the IVDs for quality control evaluation and to report the result in comparison with acceptances criteria.

7. REPORT PROCEDURE OF ADVERSE EVENTS

Where to Report

Duly filled IVD Medical Devices Serious Adverse Event Reporting Format can be sent to

- Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector 23, Rajnagar, Ghaziabad – 20002, Tel- 0120-2783400, 2783401, 2783392.
  Fax: 01202783311; or e mail to mvpi.ipcindia@gmail.com or call on
  Helpline no. 1800 180 3024.
- Medical devices and Diagnostic Division, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Directorate General of Health Services, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

Who can Report?

- All Importers, Manufacturers, Distributors, clinical laboratories, Users, healthcare clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses and technicians can report medical device adverse events (MDAEs).

Why to Report?

- As a healthcare professional or ethical medical device Importers, Manufacturers, Distributors, it is one‘s moral responsibility to report adverse events associated with use of Medical Devices, hence safeguard the health of public.

What to Report?

- To foster the habit of reporting, CDSCO and MvPI encourages reporting of all types of adverse events related to Medical Devices irrespective of whether they are known or unknown, serious or nonserious, frequent or rare though Materiovigilance is primarily concerned with adverse events associated with Medical Devices used in India

How and Whom to Report?

- Use the Medical Device Adverse Event Reporting Form which is available on the official website of IPC (www.ipc.gov.in) to report any adverse event. Reporters from MDMCs after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre.

  Reporter can also mail the scanned form at mvpi@sctimst.ac.in and copy to *mvpi.ipcindia@gmail.com*

  NCC-PvPI has also created a helpline number 1800-180-3024 to report adverse events associated with medical devices and medicines. A reporter can also call on this number to report MDAEs.

- Reporter can also be sent to Medical devices and Diagnostic Division, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Directorate General of Health Services, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

8. RECALL:

Recalls are an effective method for removing or correcting marketed products, their labeling, and/or promotional literature. Recalls afford equal consumer protection but generally are more efficient and timely than formal administrative or judicial actions, especially when the product has been widely distributed. Licensee's (Importer/Manufacturer) may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall, in response to a formal ordered issued by concern licensing authority (CLA/SLA).

Manufacturers, importers, wholesalers and registrants of medical devices are to establish and implement documented procedures:-

- to conduct effective and timely recalls;
- to ensure that defective or potentially defective medical devices are removed from the market or that measures are taken to correct the defect in an effective and timely manner;
- to ensure that any medical devices to be recalled are notified to the Authority on or before initiation of any action;

- to ensure that the Authority is made aware of their results and of the action taken to prevent recurrence of the problem.

Types of recall:

Voluntary Recalls:

If a recall is firm-initiated, the concern licensing authority will review the information provided by the recalling firm. This includes reviewing and suggesting changes to the firm's recall strategy, recall communication, and press release (if necessary) Concern licensing authority may inform a firm that a product violates the law and recommend they cease distribution and recall the product without specifically requesting a recall. If a firm decides to recall under these circumstances, the firm's action is considered a firm-initiated recall.

It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. The purpose of 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.

Statutory Recalls:

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

a) To recall the In vitro diagnostics medical devices product/batch, considered to be in violation of the regulation, it administers such as not of standard quality etc.
b) To recall the banned In vitro diagnostics devices.
c) Labelling or promotional materials that are considered to be in violation of regulation.

Establishing and Implementing Standard Operating Procedures (SOP) for In Vitro Diagnostics Medical Device Recall

The registrants and dealers of In Vitro Diagnostics medical devices are required to establish and implement documented procedures that will enable them to carry out effective and timely recalls. The recall SOP identifies all internal and external personnel involved, along with their functions and responsibilities, and sets out the channels and means of communications for executing the recall. The procedure also determines the level of priority and

assigns a time frame for completion of the recall. The written recall procedure guides the development of the recall strategy. All staff involved in an In Vitro Diagnostics Medical Device recall should be trained in the procedures and have access to a copy of the company's SOP. The possible elements that could be included in a recall SOP is outlined in Figure 2.

ELEMENTS OF A RECALL SOP

The manufacturer, importer, wholesaler and registrant will have roles in each of the elements to a varying degree.

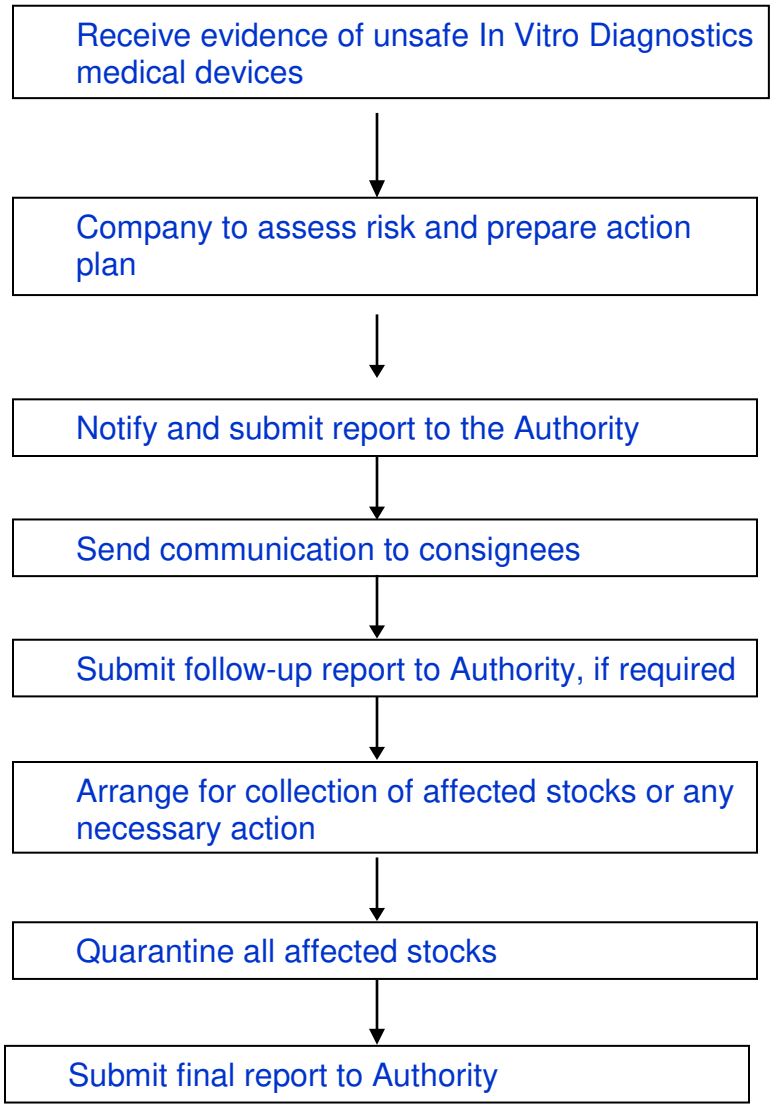

FIGURE 2- ELEMENTS OF A RECALL SOP

RECALL STRATEGY

The recall strategy is a detailed plan for implementing a company's recall procedure in a specific case. The recall strategy will address the following elements below, regarding the conduct of the recall.

a) Depth of Recall

Depending on the medical device's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:-

- Consumer or user level;
- Retail level;
- Wholesale level.

b) Recall Communications

Recall communications should be sent in the most expeditious manner and commensurate with the hazard of the product being recalled, and, where appropriate, sent with proof of receipt (e.g., by certified mail). All communication methods related to the firm's recall should be documented accordingly.

Recall communication, should include a postage-paid, self-addressed post card, envelope, or other arrangement to enable the consignee to report the amount of the product available and its disposition. Recall communications should direct that the consignee submit a report regardless of whether or not any of the products are on hand. It should also stress prompt return of the post card or other report.

Notifying the Authority of the Recall

The time frame for notification of a recall is described as "before carrying out the recall". This is satisfied by submitting as much of the recall detail as is known within 24 hours of having made the decision to recall. A preliminary report containing full information on the recall must be submitted within 24 hours from the commencement of the recall. A final report is to be submitted to the Authority within 21 days from the date of commencement of the recall.

All notification and reports are to be submitted in the manner that the Authority prescribes.

Recall communications refers to the communications sent to each of its consignees notifying them of the recall and the actions required of them. The registrant and dealers of medical devices are responsible for promptly notifying each of its consignees about the recall. A guideline on the elements that should be present in a recall communication given as follows-

ELEMENTS OF RECALL COMMUNICATION TO CONSIGNEES

The recall notice sent to all consignees notifying them of the recall should include the following:-

i. Company Particulars

- name of company
- name of contact person(s)
- contact number(s) / hotline(s) for enquiry
- fax number
- contact email address
- address

ii. Product Description

- medical device name
- model name / number
- lot / Batch numbers or serial numbers
- name of product owner
- country of manufacture
- other details to enable immediate and accurate identification of the medical device that is subject to recall

iii. Hazards Associated with the Medical device

- reasons for the recall
- nature and cause of the medical device defect
- clarification of the potential hazard associated with the continued use of the medical device and the associated risk to the patient, user or other person
- any possible risks to patients associated with previous use of affected medical devices

NOTE

- Any comments and descriptions that attempt to play down the level of risk in an inappropriate manner should be omitted.
- Misrepresent the level of risk in relation to the hazards associated with the medical device should be omitted.
- Advertise medical devices or services; should be omitted.

iv. Actions to be Taken

Examples of actions that may be taken:-

- identify and quarantine the medical device
- cease the use of the medical device immediately
- cease the sale /distribution of the medical device immediately
- method of recovery, disposal or modification of the medical device
- recommended patient follow up
- Return confirmation form to the product owner if an action is required. (e.g. return of medical devices)

v. Other Details

- a request to pass the recall notice to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period
- date of recall letter

NOTE:
Any comments and descriptions that attempt to:-

c) Effectiveness checks

The firm initiating the recall should verify that consignees have received notification about the recall and have taken appropriate action and perform effectiveness checks. The firm initiating the recall may conduct effectiveness checks through personal visits, telephone calls, facsimiles, letters or a combination of various means.

d) Stock Control

The firm initiating the recall is responsible for ensuring that the medical device returned to it is properly identified and isolated until a decision has been made with approval from Authority on its eventual fate. Such a decision may include disposal of medical devices, return of medical devices to the product owner or correction of medical devices. The recalled medical device must not be put back on the market unless the Authority gives authorisation.

Public Warning:

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. Firm may wish to issue public recall announcement, such as a press release, for a recall whose hazard level does not meet the threshold for a public warning.

ANNEXE-1

Recall Notification Letter
Company Letterhead

Date (Month, Day, Year)

URGENT

RECALL NOTICE

Contact Name
Firm Name
Address
City, State, Pin Code

Subject: Recall of product NAME, BRAND NAME, DESCRIPTIONS, CODES, LOT NUMBERS MANUFACTURER NAME AND ADDRESS, LICENSE NUMBER AND ETC.]

Dear [Insert Customer/Distributor/Manufacturer, etc.], this is to inform you of a product recall involving [Insert: PRODUCT NAME, BRAND NAME, DESCRIPTIONS, CODES, LOT NUMBERS MANUFACTURER NAME AND ADDRESS, LICENSE NUMBER AND ETC.]
See enclosed product label [for ease in identifying the product at retail/user level].
This recall has been identified due to [problem].Use of [or consumption of] this product may [include any potential health hazard].
We began shipping this product on [date].Use of [or consumption of] this product may [include any potential health hazard].
Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or [Enclosed is a letter you should use in notifying your customers].
[Your notification must include instructions on what customers should do with the recalled product.]
This recall should be carried out to the [wholesale], [retail], [consumer], [user] level.
Your assistance is appreciated and necessary to prevent [i.e. consumer illness or patient harm].

Please complete and return the enclosed response form as soon as possible. If you have any questions, call [name and telephone number].
Name:
Signature:
NOTE: This annexe is intended to serve as guidance for recalling firms. Please make any appropriate modifications to the form as per the requirement.

ANNEXE-2

Recall Return Response Form

[COMPANY LETTER HEAD]

Insert [Product] Insert [Lot numbers]
Insert [Product] Insert [Lot numbers]
Please check ALL appropriate boxes.

❑ I have read and understand the recall instructions provided in the [date of] letter.

❑ I have checked my stock and have quarantined inventory consisting of [ ] units or cases /number of kits/tests.

❑ Indicate disposition of recalled product:

- ❑Returned (specify quantity, date and method)/held for return;
- ❑Destroyed (specify quantity, date and method);
- ❑Relabeled (specify quantity and date);
- ❑Quarantined pending correction (specify quantity);
- ❑Distributed (specify quantity and date);
- ❑Used (specify quantity and date)

Attached is a list of customers who received/ may have received this product. Please notify my customers.
Any adverse events associated with recalled/failed product? ❑Yes ❑ No

If yes, please explain:----------

I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of _____ [units, cases, /number of kits/tests etc.].
Please check the appropriate box(es) to describe the nature of your business:

❑Wholesaler/distributor	❑ Food service/restaurant
❑ Grocery corporate headquarters	❑Manufacturer
❑ Repacker	❑ Hospital/Medical facility
❑ Pharmacy-retail	❑Medical laboratory
❑ Hospital pharmacies	❑ Retailer

❑Other: (Specify) ----------
Name:
Signature:
NOTE: This annexe is intended to serve as guidance for recalling firms. Please make any appropriate modifications to the form as per the requirement

Adverse Event reporting Form – Attached

Field Safety Corrective Action Notification (FSCA) Form-Attached

ANNEXE-3

IVD COMPLAINT REPORTING FORM

USER COMPLAINT FORM FOR REPORTING COMPLAINTS AND/OR ADVERSE EVENTS RELATED TO IN VITRO DIAGNOSTICS

This form is intended to collect information on IVD Medical Devices' Adverse Events in India.

The form is designed to be used by Manufacturer/ Importer/Distributor/user of an IVD Medical Device/ Govt. process manager/Healthcare Professional and anyone with direct/ indirect knowledge of an IVD Medical Device Adverse Event.

Primary information				
1. Date of Report :				
2. Type of Report :	Initial ❑	Follow up ❑	Final ❑	Trend ❑
3. Reporter Reference No. :				

1. Details of the reporting person/organization

Reporter category:

- ❑ **Manufacture**
- ❑ **Central / State Govt. Programming Officer**
- ❑ **Importer**
- ❑ **Distributor**
- ❑ **Patient**
- ❑ **Healthcare Professional**
- ❑ **Other (specify)----------**

Name of person/organization:	**Street Name and No.:**
City and postcode:	**Country:**
Telephone:	**Fax:**
Name and position of contact person:	**Email of contact person:**

2. Product Category

- ❑ IVD Kit
- ❑ IVD Reagents
- ❑ Calibrator
- ❑ Control
- ❑ POCT/ Home use IVD Device
- ❑ Instrument / Analyzer
- ❑ Other (specify)----------

2.a. Product details

Product name/commercial name/brand name:	**Product code (catalogue number)(s):**
Is the Device regulated in India? ❑ YES ❑ NO ❑ Unknown	
Device Risk Classification as per Indian MDR 2017 : ❑ Class A ❑ Class B ❑ Class C ❑ Class D ❑ Unknown	
Lot number/batch number/serial number:	**Mfg date:** **Expiry date:** **Storage Temperature:**
IVD Kit component name	**Lot number/batch number/serial number:** **Mfg date:** **Expiry date:** **Storage Temperature:**
Associated devices/accessories (lot numbers/expiry dates):	**Instructions for use version number:**
Import license Number	**Manufacturing license Number**
Importer name and address:	**Manufacturer name and address:**
Distributor name and address:	

Please attach a copy of the instructions for use.

Please attach a copy of the Purchase Bill / Invoice.

Availability of device for evaluation : ❑ Yes ❑ No **If No, was the device**
Destroyed ❑ Still in use ❑ Returned to the manufacture or importer/distributor ❑
Is the usage of device as per manufacturer's claims/ Instructions for use/user manual : **❑ Yes ❑ No**
If no specify usage……..
Was the IVD Medical device stored at the recommended temperature at all times? **❑ Yes ❑ No**
Was the patient sample (blood/urine/sputum etc.) obtained & stored as per recommendation of the Manufacturer? **❑ Yes ❑ No**
Was the procedure for conducting the IVD test meticulously followed as per the product Insert/instructions for use, provided by the manufacturer? **❑ Yes ❑ No**
Was the test result obtained with the IVD device confirmed by using a confirmation test? **❑ Yes ❑ No**

Event/problem details

Event/problem description narrative (explain what went wrong with the product and the observed or likely/probable consequences):	
Date of the event/problem:	**Number of tests involved:**
Event location: **❑Pathology Lab** **❑Manufacturer's/ Distributor's premise**	
❑Hospital Premise **❑Home**	**% of tests involved :**

❑others specify----------	Number of patients involved:
Operator/user at the time of the event/problem (please choose): ❑Laboratory technician/technologist ❑(Non-laboratory) health worker	Has more than one user experienced the problem with the product? ❑Yes ❑No
Type of specimen used (please specify):	State reading time used:
Have you informed the distributor? ❑Yes ❑No	Date: What measures have been recommended?
Have you informed the manufacturer? ❑Yes ❑No	Date: What measures have been recommended?
Measures taken by the operator/user:	
Device's Current Location : Returned to Company ❑Yes ❑No If yes, (DD/MM/YY) ...../...../..... Within the Pathology Lab /healthcare facility ❑ At Patient's home ❑ Destroyed ❑ Others (Specify)----------	
Serious Event : Death ❑Yes ❑No If yes, (DD/MM/YY) ……/…../… Life Threatening ❑ Disability or Permanent damage ❑ Hospitalization ❑ Congenital anomaly/birth defect ❑	
Is device in use after the incidence : ❑Yes ❑No	
Comments:	

Date of report:	**Signature:**

Frequency of occurrence of serious Adverse Event/s in India in the past 3 years	**Year**	**No. of Similar Adverse Events**	**Total No. Supplied**	**Frequency of Occurrence (%)**
10. Frequency of occurrence of serious Adverse Event/s globally in past 3 years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

ANNEXE-4

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION (FSCA) FORM: IVD medical devices

1. Before filling this form, the reporter collects and collates the prescribed information in the form.

2. This form will serve as the reporting tool in lieu of the Medical Devices Rules; 2017. Fourth Sc(2), 21(2), 34 (2), 63(1) and 64(1) Part (ii) (b) and Appendix II for intimating, notifying CDSCO for any Field safety Corrective Action (FSCA) in relation to an IVD medical device product recall and other corrective action.

3. A scanned signed copy of PDF version of this form is to be sent to CDSCO via email to dci.nic.in.

4. Additional information that may be pertinent for the completion of this form can be provided as an attachment.

5. All the field safety notices will be published on the CDSCO website and the reporter shall hold the full responsibility for the information contained in the Field Safety Notification and the reporter must indemnify CDSCO for all losses, claims, demand, liabilities, causes of action, expenses of any kind arising from CDSCO's publication of the FSN.

	Primary information			
1.	**2. Type of field safety corrective Action (FSCA)** Product Recall ❑Yes ❑No If yes, (DD/MM/YY) ...../...../..... **Other Corrective actions (specify):----------**			
2. Type of Report :		Preliminary ❑	Follow up ❑	Final ❑
	3. Reporter Reference No. :			
	Date of Report (dd/mm/yy)			

Details of Submitter of Information		
1	Name of company submitting information	
2	Company Address	
3	Contact person particulars (Name, Email and Tel No.)	

4	Job Title	
5	Telephone Number/s	
6	e-mail Address	
7	Local Contact Details (if reporter not based in India)	

2. Product details

Product name/commercial name/brand name:	**Product code (catalogue number)(s):**
Is the Device regulated in India? ❑ **YES** ❑ **NO** ❑ **Unknown**	
Device Risk Classification as per Indian MDR 2017 : ❑ **Class A** ❑ **Class B** ❑ **Class C** ❑ **Class D** ❑ **Unknown**	
Lot number/batch number/serial number:	**Mfg date:** **Expiry date:** **Storage Temperature:**
IVD Kit component name	**Lot number/batch number/serial number:** **Mfg date:** **Expiry date:** **Storage Temperature:**
Associated devices/accessories (lot numbers/expiry dates):	**Instructions for use version number:**
Import license Number	**Manufacturing license Number**
Importer name and address:	**Manufacturer name and address:**
Distributor name and address:	

Please attach a copy of the instructions for use.

Please attach a copy of the Import / Manufacturing license.

FSCA Information					
Background information and reason for the FSCA:					
Description and justification of action (corrective/preventive):					
Date complaint reported to manufacturer (and/or distributor):					
Advice on actions to be taken by distributor and the user:					
Field Safety Notice attached: ❑Yes ❑No					
Time schedule for implementation of different actions:					
List of countries this FSCA has been distributed to:					
1	Number of affected units and the period that affected units are manufactured/imported/supplied in India	Manufactured in India			
		Period	(mm/yyyy)	to	(mm/ yyyy)
		Imported into India			
		Period	(mm/yyyy)	to	(mm/ yyyy)
		Supplied in India			
		Period	(mm/ yyyy)	to	(mm/ yyyy)
		Expected shipment to India			
		Expected Date of Arrival			(mm/ yyyy)
2	Number of affected units supplied to each consignee along with copy of Invoices and Import Bill of Entries				
3	FSCA Strategy				
4	Did the FSCA arise due to an adverse event? **❑Yes ❑No**				

5	If Yes, What is the category of adverse event? Death ❑ Serious Injury ❑ Serious Public Health Threat ❑ Non- Serious Injury ❑
6	Did this adverse event occur in India **❑Yes ❑No** If Yes, then adverse event Ref. No. & Summary
7	Evaluation of risk associated with affected device (Health Hazard Evaluation Report)
8	Give reason & detail for FSCA (if other than the adverse event)

Affected Device Details (e.g. device identifiers, lot/batch No.) listed in the FSCA Communication	
For other than India:	
1	Has the FSCA Communication been sent to all consignees?
2	Date of commencement of FSCA by product owner (dd/mm/yyyy)
3	Date of commencement of FSCA (if applicable)
4	Countries to which FSCA has been reported (if any)
5	Proposed date of completion of FSCA (if applicable)
6	Summary of root cause analysis
7	Summary of Corrective and Preventive Action (CAPA)

For India:					
1	Affected device details				
2	Has the FSCA Communication been sent to all consignees?	Yes Date Sent : (dd/mm/yyyy)		No (dd/mm/yyyy)	
3	Date of commencement of FSCA by product owner (dd/mm/yyyy)				
4	Date of commencement of FSCA in India(if applicable)				
5	Countries to which FSCA has been reported (if any)				
6	Proposed date of completion of FSCA (if applicable)				
7	Summary of root cause analysis				
8	Summary of Corrective and Preventive Action (CAPA)				

Change Notification (if applicable)	
1	Labeling Change Procedure change Shelf life change etc.

Other Information

I attest that the information submitted is true and accurate and that I am authorized to submit this form on behalf of the company.

Signature : .....

Name of reporting person : .....

Date of Notification : .....