



**RECALL, ADVERSE EVENT and POST-MARKETING VIGILANCE REPORTING of MEDICAL DEVICES and IVDs**

This guideline is intended to provide recommendations to Manufacturers, Importers, Exporters, Distributors and Holders of Certificate of Registration (HCR) of medical devices and IVDs. It represents the Authority’s current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. The Authority reserves the right to request any additional information to establish the safety, quality and performance of a medical device or IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Authority is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the CEO and the website.

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**Chief Executive Officer**

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## GUIDELINE FOR RECALL / WITHDRAWAL, ADVERSE EVENTS & POST-MARKETING VIGILANCE REPORTING OF MEDICAL DEVICES AND IVDs

**NOTE:** This guideline outlines the format and data requirements for reporting of adverse events and post-marketing vigilance and monitoring requirements for Medical Devices and IVDs, and should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the Regulations to this Act

### 1 INTRODUCTION

The registration of medical devices and IVDs in South Africa is governed by the provisions and requirements of the Medicines and Related Substances Act No. 101 of 1965, (hereafter 'the Act') and the Regulations and Guidelines published in terms thereof.

Copies of the legislation can be obtained from the SAHPRA website [www.sahpra.org.za](http://www.sahpra.org.za)

This guideline provides a reference document detailing the regulatory requirements for reporting of adverse events, post-marketing vigilance and monitoring requirements and recall of medical devices and IVDs in South Africa and describes the information to be supplied to the Regulatory Authority in South Africa.

The information submitted will be evaluated in terms of the provisions of the Act.

The aim of this guideline is to assist licensed manufacturers, importer, distributors and wholesalers and the holders of registration certificates (HCR) in the reporting of adverse events, the post-marketing vigilance and monitoring of medical devices or IVDs and recall of medical devices and IVDs from the market.

The types of medical devices or IVDs include all products classified as per the different Classes based on a risk assessment and intended use.

All medical device or IVDs for supply in South Africa must continue to meet all the regulatory, safety and performance requirements and any applicable standards.

Whenever there is doubt, applicants are advised to consult the Regulatory Authority(SAHPRA) for confirmation and/or clarification regarding reporting; refer to the website for contact details.

Persons should refer to the **current** version of the relevant **GUIDELINE FOR RECALL, ADVERSE EVENTS & POST-MARKETING VIGILANCE REPORTING OF MEDICAL DEVICES AND IVDs** and the annexures thereto when reporting.

Guidelines are constantly evolving as a result of scientific developments and harmonisation of the requirements of regional and international regulatory authorities. The Regulatory Authority (SAHPRA) endeavours to regularly update the guidelines to reflect current thinking and keep its technical requirements and evaluation policies in line with “best international medical device and IVD regulatory practice”.

## 2 GENERAL

### 2.1 Scope

A medical device and IVD is defined as per the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended. Legislation requires that a medical device or IVD shall comply with the Essential Principles of Safety and Performance of Medical Devices and IVDs which include requirements for quality, safety and performance as determined by the Regulatory Authority.

This guideline is intended to assist licensed manufacturers and distributors and Holders of a Certificate of Registration (HCR) of Medical Devices and IVDs in

- the reporting of adverse events associated with the use of medical devices and IVDs,
- the post-marketing vigilance for medical devices and IVDs. (This includes the management of safety data which arises during post-registration and post-marketing performance and clinical trials.) and
- the recall of a medical device or IVD from the market place.

If there is a problem with a medical device or the way in which it is being used, the Holder of the Certificate of Registration (HCR) and the licensed manufacturer or licensed distributor will first conduct an analysis and decide on the appropriate action. One of these actions may require notifying or obtaining further advice from the Regulatory Authority. Some actions that may need to be taken could include to:

- follow corrective actions / preventive actions procedures under the manufacturer 's / distributor's quality management system,
- inform the users of the device or IVD,
- make corrections to the device or IVD,
- remove, i.e. recall the medical device or IVD from the market.

The Regulatory Authority has established procedures for the ongoing monitoring, vigilance and recall for medical devices and IVDs supplied in South Africa.

These guidelines are relevant only to medical devices and IVDs. Separate guidelines apply to the reporting of adverse events and pharmacovigilance of human medicines including biological and complementary medicines.

### 2.2 Definitions

***Refer to the General Regulations relating to Medical Devices and IVDs and the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended***

***Quarantined Stock (in the context of a recall)*** – means the stock of product that has been put on hold for destruction or rework. The stock has been released for sale and has not yet been dispatched or has not left the direct control of the holder of a certificate of registration (HCR) / licensed manufacturer / licensed distributor.

***Recall*** - means the removal of specific batch/batches or lot/lots or serial number/s of a medical device or IVD from the market for reasons relating to deficiencies in the quality, safety or performance.

***Withdrawal*** - means the total withdrawal of a medical device or IVD from the market.

### 3 PROVISIONS OF THE ACT

Refer to the General Regulations relating to Medical Devices and IVDs and to the Medicines and Related Substances Act, Act 101 of 1965.

### 4 VIGILANCE

The purpose of medical device post-market vigilance is to improve the health and safety of patients, users, and others by reducing the likelihood of adverse events being repeated. This can be achieved by:

- evaluating reported adverse events
- disseminating information that could be used to prevent or minimise the consequences of adverse events, where appropriate
- modifying the device or IVD
- removing the medical device or IVD from the market

Action is undertaken by the Regulatory Authority and the HCR and/or licensed manufacturer and /or licensed distributor after any party becomes aware of information about a medical device or IVD supplied in South Africa, such as:

- adverse event reports
- malfunctions
- results of testing
- any other information

The HCR or licensed manufacturer or licensed distributor must inform the Regulatory Authority of all reportable adverse events, within the appropriate timeframes. They must also ensure timely and appropriate action is taken.

To improve the monitoring of the performance of devices supplied in South Africa, the Regulatory Authority encourages the reporting of adverse events by users of medical devices and IVDs.

#### 4.1 Vigilance Exchange

Through various Mutual Recognition Agreements for medical device and IVD regulation, the Regulatory Authority has an obligation to exchange vigilance information with other national regulatory authorities. Information will be exchanged on incidents and events where:

- corrective action, including a recall, is to be taken
- there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined.

The Regulatory Authority will consult the HCR or licensed manufacturer or licensed distributor when preparing a vigilance report to be sent to other regulatory authorities. It is the responsibility of the HCR or licensed manufacturer or licensed distributor to ensure that the primary manufacturer is aware of the Regulatory Authority vigilance report, and that any comments that are made by the primary manufacturer are submitted to the Regulatory Authority for consideration.

Regulatory authorities generally use discretion where a manufacturer takes corrective action that is not considered to be essential to protect the safety of patients or others. Examples of this are minor improvements to current devices and updates of user information. In the case of doubt, however, a regulatory authority will generally disseminate information.

## 5 ADVERSE EVENTS

The HCR / licensed manufacturer / licensed distributor is legally responsible for the supply of the medical devices and IVDs in South Africa, including the receipt and handling of complaints and adverse events. The HCR or licensed manufacturer or licensed distributor may receive event reports from users, the Regulatory Authority, the primary manufacturer, distributor or other sources, e.g., literature, consumer bodies, professional bodies. The HCR / licensed manufacturer / licensed distributor must forward copies of all reports to the primary manufacturer (international or local) and copies of all reportable adverse event reports to the Regulatory Authority.

The HCR / licensed manufacturer / licensed distributor must maintain records of any complaints/incidents that occur involving a medical device or IVD that they manufacture or import and that is supplied in South Africa. The HCR / licensed manufacturer / licensed distributor must inform the Authorised Representative of any reports from users or other information that indicates there is a possible problem with a device supplied in South Africa.

The Regulatory Authority must be notified of any incidents that occur in South Africa and that are considered adverse events (see below for an explanation of what is considered an adverse event). The Regulatory Authority will forward details of an incident and the device in the reports from users to the Authorised Representative of the HCR / licensed manufacturer / licensed distributor of the medical device.

### 5.1 Reportable Adverse Events

Any event that meets three basic reporting criteria, even if it does not involve a patient or user, should be reported to the Regulatory Authority:

- an adverse event has occurred
- the licensed manufacturer's or licensed distributor's medical device is associated with the adverse event
- the event led to or might lead to (often referred to as a near adverse event) death or serious injury, or might lead to death or serious injury if it were to occur again.

An adverse event is an event that may lead to:

- death, or
- a serious injury or serious deterioration to a patient, user or other person, including
  - a life-threatening illness or injury
  - permanent impairment of a body function
  - permanent damage to a body structure
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

A 'near adverse event' is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:

- an event associated with the device happened
- if the event occurred again, it might lead to death or serious injury
- testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

Typical adverse events are as follows:

Event or cause of an adverse event	Description
Malfunction or deterioration in the characteristics or performance of a medical device	Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions <i>Please note: intended purpose means the intended use according to the data supplied to the Regulatory Authority by the manufacturer on the labelling, in the Instructions for Use and/or in advertising materials</i>
Inadequate design or manufacture of a device	Design or manufacturing of a device is found deficient
Inaccuracy in the labelling, <i>Instructions for Use</i> and/or promotional materials	Inaccuracies include omissions and deficiencies Omissions do not include the absence of information that should generally be known by the intended users
Significant public health concern	Can include an event that is of significant and unexpected nature that becomes a potential public health hazard, for example, human immunodeficiency virus (HIV) or Creutzfeldt–Jacob Disease (CJD) The Regulatory Authority, Authorised Representative, or the manufacturer may identify these concerns
Other information becoming available	Can include: <ul style="list-style-type: none"> <li>• information from the literature or other scientific documentation</li> <li>• the results of testing performed by the manufacturer on its products</li> <li>• reports from the user prior to the device being used on the patient</li> </ul>

## 5.2 Reporting Incidents with Medical Devices

The reporting requirements for Authorised Representative of the HCR / licensed manufacturer or the licensed distributor are conditions on the sale of medical devices or IVDs in South Africa. Breaching conditions may lead to suspension or cancellation of the sale of device as well as constituting an offence.

The Authorised Representative of the HCR / licensed manufacturer or the licensed distributor is responsible for forwarding reports of all incidents to the primary manufacturer or distributor for assessment under the primary manufacturer's and distributor's surveillance systems.

It is possible that the HCR / licensed manufacturer or the licensed distributor will not have enough information to decide if the problem should be reported to the Regulatory Authority. The Authorised Representative of the HCR / licensed manufacturer or the licensed distributor should make reasonable efforts to obtain additional information to assist in making this decision.

In assessing the link between the device and the event, the Authorised Representative and or HCR should take into account:

- the opinion, based on available information, from a health professional
- information concerning previous, similar events
- other information held by the Authorised Representative, or HCR / licensed manufacturer and licensed distributor.

In complex situations, it should be assumed that the device was associated with the event. If there is any doubt about whether a report should be submitted, the report should be submitted.

Where possible, the Authorised Representative of the HCR / licensed manufacturer / licensed distributor should consult with the user and/or medical practitioners or other healthcare professionals involved, and do their utmost to retrieve the particular device.

Reporting of events or near events by users is voluntary. The Regulatory Authority promotes and encourages users to report. Device users are encouraged to report events associated with the use of a medical device to the HCR and the Regulatory Authority.

#### EXAMPLES OF REPORTABLE ADVERSE EVENTS

- The premature revision of an orthopaedic implant due to loosening or fracture
- An infusion pump stops, due to a malfunction, but fails to give an alarm. The patient receives an under-infusion of needed fluids
- During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to a malfunction
- An intravenous set separates and the comatose patient's blood leaks onto the floor, resulting in significant blood loss

#### EXAMPLES OF REPORTABLE ADVERSE EVENTS INVOLVING PUBLIC HEALTH CONCERNS

- Fatigue testing performed on a commercialised heart valve bioprosthesis demonstrates premature failure, which would indicate that a risk to public health could occur
- After delivery of an orthopaedic implant, errors were discovered in heat treatment records raising questions about the effectiveness of the implant's materials that would create a risk to public health
- A manufacturer provides insufficient details on cleaning methods for reusable surgical instruments used in brain surgery, despite the obvious risk of transmission of CJD

Only adverse events that occur in South Africa are required to be reported to the Regulatory Authority. Adverse events for Class A and B medical devices that occur outside of South Africa for devices supplied in South Africa do not need to be reported to the Regulatory Authority. However, records of these events should be available if requested. Also, any remedial action that arises outside of South Africa for Class C and D medical devices supplied in South Africa should be reported.

### 5.3 Exemptions from Reporting Adverse Events to the Regulatory Authority

There are eight exemption rules that can apply (see table of exemption rules overleaf).

However, these rules do NOT apply when:

- a device, event or issue specifically identified by the Regulatory Authority as an issue that requires close monitoring—applicants of devices that are affected will be notified by the Regulatory Authority when this occurs
- an adverse event normally subject to a reporting exemption, where a change in trend (usually an increase in frequency) or pattern is identified
- adverse events associated with user error, as the Regulatory Authority may use this data to identify trends with similar products that may lead to recommendations for:
  - corrective action for the device
  - revising the labelling or *Instructions for Use*
  - identifying a need for increased user education.

If a manufacturer believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented.



EXEMPTION RULES FROM REPORTING ADVERSE EVENTS TO THE REGULATORY AUTHORITY

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
1	<p>Deficiency of a new device found by the user prior to its use</p> <p>Regardless of the existence of provisions in the Instruction for Use provided by the manufacturer, deficiencies of devices that will be always detected by the user and where no serious injury has occurred, do not need to be reported.</p> <p><i>Please note: If the device is used the exemption does not apply—the event must be reported.</i></p>	<p>A user performs an inflation test (standard procedure) prior to inserting the balloon catheter in the patient as required in the <i>Instructions for Use</i> accompanying the device. Malfunction on inflation is identified. Another balloon is used. Patient is not injured.</p> <p>Sterile single-use device packaging is labelled with the caution ‘do not use if package is opened or damaged’. Open package seals are discovered prior to use, device is not used.</p> <p>An intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.</p>
2	<p>Adverse event caused solely by patient conditions</p> <p>When the manufacturer has information that the root cause of the adverse event is due to patient condition, the event does not need to be reported. These conditions could be pre-existing or occurring during device use.</p> <p>To justify not reporting, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to a death or serious injury. A person qualified to make a medical judgement would accept the same conclusion.</p>	<p>An orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision.</p> <p>The early revision of an orthopaedic implant due to loosening caused by the patient developing osteoporosis.</p> <p>A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure.</p>
3	<p>Service life of the medical device</p> <p>The service life is defined as ‘<i>the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified</i>’. The service life must be specified by the device manufacturer and included in the master record (technical file).</p> <p>When the only cause for the adverse event was that the device exceeded its service life and the failure mode is not unusual, the adverse event does not need to be reported.</p> <p>Assessment of whether an event is exempt from reporting under this rule must be based on the information in the master record, on the label or in <i>Instructions for Use</i> for the device.</p>	<p>Loss of sensing after a pacemaker has reached its end of life. The elective replacement indicator has shown up in due time according to the device specification. Surgical explanation of pacemaker is required.</p> <p>A drill bit was used beyond the end of its specified life. It fractured during invasive operation. Operation time was prolonged due to the difficulty to retrieve the broken parts.</p>

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
4	<p>Protection against a fault functioned correctly</p> <p>Adverse events that did not lead to serious injury or death, because a design feature protected against a fault becoming a hazardous situation (in accordance with relevant standards or documented design inputs) do not need to be reported.</p>	<p>An infusion pump stops, due to a malfunction, but gives an appropriate alarm (for example, in compliance with relevant standards) and there was no injury to the patient.</p> <p>Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm, in compliance with relevant standards and there was no injury to the patient.</p> <p>During radiation treatment, the automatic exposure control is engaged and the treatment stops. Although the patient receives less than an optimal dose, the patient is not exposed to excess radiation.</p>
5	<p>Remote likelihood of occurrence of death or serious injury</p> <p>Adverse events that could lead, but have not yet led, to death or serious injury, but have a remote likelihood of causing death or serious injury, and which have been established and documented as acceptable after risk assessment do not need to be reported.</p> <p>If an adverse event resulting in death or serious injury occurs, the adverse event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains remote, previous reports of near incidents of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented.</p> <p>Please note: A change in the trend (usually an increase in frequency) of these non-serious outcomes must be reported.</p>	<p>The manufacturer of a pacemaker supplied to the market identified a software bug and determined that the likelihood of occurrence of a serious injury with a particular setting is remote. No patients experienced any adverse health effects.</p> <p>The manufacturer of blood donor sets obtains repeated complaints of minor leaks of blood from these sets. No patient injuries from blood loss or infections of staff have been reported. The chance of infection or blood loss has been re-evaluated by manufacturer and deemed remote.</p>
6	<p>Expected and foreseeable side effects that are documented in manufacturer's Instructions for Use or labelling</p> <p>Side effects that are clearly identified in the manufacturer's labelling or are clinically well known as being foreseeable and having a certain functional or numerical predictability when the device was used as intended need not be reported.</p> <p>Some of these events are well known in the medical, scientific, or technology fields. Others may have been clearly identified during clinical investigation and labelled by the manufacturer.</p> <p>Documentation, including the risk assessment, for the particular side effect</p>	<p>A patient receives a second-degree burn during the use of an external defibrillator in an emergency. The risk assessment documents that such a burn has been accepted in view of the potential patient benefit and a warning is provided in the <i>Instructions for Use</i>. The frequency of burns is occurring within range specified in the device master record.</p> <p>A patient has an undesirable tissue reaction that is previously known and documented in the device master record.</p> <p>A patient who has a mechanical heart valve developed endocarditis ten years after implantation and then died.</p>

Rule No.	Exemption Rule	Examples of adverse events exempt from reporting
	<p>should be available in the device master record prior to the occurrence of adverse events. The manufacturer cannot conclude in the face of events that they are foreseeable unless there is prior supporting information.</p>	<p>Placement of central line catheter results in an anxiety reaction and shortness of breath. Both reactions are known and labelled side effects.</p>
7	<p>Adverse events described in an advisory notice Adverse events that occur after the manufacturer has issued an advisory notice need not be reported individually if they are specified in the notice. Advisory notices include removals from the market, corrective actions, and product recalls. The manufacturer should provide a summary report, the content and frequency of which should be agreed with the Regulatory Authority.</p>	<p>A manufacturer issued an advisory notice and undertook a recall of a coronary stent that migrated due to inadequate inflation of an attached balloon mechanism. Subsequent examples of stent migration were summarised in quarterly reports required for the recall action and individual adverse events did not have to be reported.</p>
8	<p>Reporting exemptions granted by the Regulatory Authority Upon request by the applicant, common and well-documented events may be exempted by the Regulatory Authority from reporting or changed to periodic reporting on a case by case basis.</p>	

#### **5.4 TIMEFRAMES FOR SUBMITTING ADVERSE EVENTS REPORTS TO REGULATORY AUTHORITY**

With reference to Regulation 17 of the Act, the period in which a person in relation to whom a kind of medical device is included in the Register must give information to the Regulatory Authority is:

- if the information relates to an event or other occurrence that represents a serious threat to public health - 48 hours after the person becomes aware of the event or occurrence; and
- if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person – 10 calendar days after the person becomes aware of the event or occurrence; and
- if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person - 30 days after the person becomes aware of the event or occurrence.

#### **5.5 DETAILS TO BE INCLUDED IN AN ADVERSE EVENT REPORT**

The following information to be included in the adverse event report form:

- 5.5.1 data relating to the Authorised Representative or HCR's:
  - name
  - address
  - telephone number
  - fax number
  - E-mail address
- 5.5.2 the date when the incident came to the knowledge of the:
  - licensed manufacturer
  - licensed distributor
  - Authorised Representative/HCR
- 5.5.3 information about the device including the:
  - kind and type of medical device
  - commercial name
  - catalogue number
  - GMDN code
  - Medical Device or IVD registration number (if applicable) issued by the Regulatory Authority
  - model number
  - serial number
  - batch number
  - lot number
  - software version (if applicable)
- 5.5.4 if implantable, date of implant and if applicable, date of explant
- 5.5.5 any associated devices and/or accessories involved in the incident

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- 5.5.6 the known details of the event, including the date and patient, health professional's name and contact details or user details, and the outcome
- 5.5.7 the current known location of the medical device involved in the event
- 5.5.8 the contact point of the user where the event occurred. The patient's full identity should not be reported. The contact point need not necessarily be a person who actually witnessed the event.
- 5.5.9 any HCR / licensed manufacturer, or licensed distributor comments
- 5.5.10 the action taken or proposed action and timeframe
- 5.5.11 a statement of whether the HCR / licensed manufacturer or licensed distributor are aware of the same type of events having an impact on the current report. The statement should include the:
  - o names of any other regulatory authorities to which these events have been reported
  - o date of the reports
  - o number of similar events
  - o number of devices supplied
  - o rate of similar events, if available
  - o any other countries in which the medical device is known to be on sale or supplied

Reports should be submitted to the Chief Executive Officer, Private Bag X828, Pretoria.

The report should not be unduly delayed if the information is incomplete. It is important to get this process underway as additional information can be provided later.

## **5.6 ACCESS TO MEDICAL DEVICES INVOLVED IN ADVERSE EVENTS**

Where possible, the Authorised Representative of the HCR / licensed manufacturer / licensed distributor, should consult with the medical device user about the event before a report is submitted to the Regulatory Authority. The HCR / licensed manufacturer / licensed distributor may also wish to have access to the medical device involved in the event to help decide whether the event should be reported to the Regulatory Authority. Such access would be at the discretion of the user or healthcare facility concerned, but they are advised to assist the HCR / licensed manufacturer / licensed distributor to determine the root cause of the incident.

If the HCR / licensed manufacturer / licensed distributor has access to the medical device, and the initial assessment or cleaning or decontamination process will involve altering the device in a way that may affect subsequent analysis, the HCR / licensed manufacturer / licensed distributor should, through the Authorised Representative, inform the Regulatory Authority before proceeding.

The Regulatory Authority advises release of the medical device to the HCR / licensed manufacturer / licensed distributor so that they can complete their analysis, which may require the assistance of the primary manufacturer.

The outcome of any investigation may include one or more:

- referral to other areas of the Regulatory Authority for regulatory actions, such as auditing of the manufacturer
- recall of the devices to:
  - o remove the devices from supply in South Africa
  - o allow correction at the user's site

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- the issue of a Safety Alert where there is a need to reinforce the manufacturer's *Instructions for Use* to those responsible for the use of the device or those affected by the problem
- product improvement for problems that are not safety-related - carried out by the manufacturer
- report on the Regulatory Authority website and/or appropriate communication

## 6 QUALITY DEFECTS OF MEDICAL DEVICES AND IVDs

If the HCR / licensed manufacturer / licensed distributor is contemplating any of the following:

- correcting product on the market
- removing product from the market, or
- advising users of an issue with a medical device

contact the Vigilance Unit at the office of the CEO for advice.

When the need for a recall of a medical device supplied in or exported from South Africa has been established, the HCR / licensed manufacturer / licensed distributor of the affected device is responsible for the recovery of the devices.

Refer to Sections 8 to 14 below for guidance on the process and requirements to conduct a recall.

## 7 NON-RECALL ACTIONS FOR MEDICAL DEVICES & IVDs

Where the HCR / licensed manufacturer / licensed distributor is unsure of the appropriate action to be taken, and particularly in cases where patient safety may be a consideration, the issues involved should be discussed with the office of the Chief Executive Officer: Recall officer.

Other action may be taken by the HCR / licensed manufacturer / licensed distributor voluntarily that is not considered to be a recall:

Action	Description
Safety Alert	Intended to provide information on safe use of devices, as distinct from recall action, which addresses product deficiencies.  Issued to provide additional advice to health professionals in situations where the device, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of substantial harm if certain specified precautions or advice are not observed. For example, specific precautions about the longevity of an implanted medical device.
Product Notification	Issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences.
Product Withdrawal	HCR's / licensed manufacturer's / licensed distributor's removal from supply or use of devices for reasons not related to their quality, safety or performance.
Product Recovery	The HCR / licensed manufacturer / licensed distributor recovers devices that have been manufactured or imported but not yet supplied to the market. For example, recovery of devices in a warehouse.
User information	Generally conducted by the HCR / licensed manufacturer / licensed distributor in response to issues with the use of a medical device or IVD.  Includes in-house sessions, seminars and improved educational materials such as posters.

## **8 NOTIFICATION / INITIATION OF A RECALL**

The recall of a medical device or IVD can be initiated as a result of reports referred to the HCR / licensed manufacturer / licensed distributor or Regulatory Authority (SAHPRA) from various sources, e.g. primary manufacturers, wholesalers, retail and hospital pharmacists, doctors. A report may relate to *inter alia* an adverse event to a particular batch(es), serial number(s), version(s), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, counterfeit including faulty medical devices or IVD or where performance of a medical device or IVD is not as intended.

When initiating a recall, the HCR / licensed manufacturer / licensed distributor should take the extent of public warnings and the successfulness of the recall into consideration.

It is imperative that before or upon initiating a recall, the HCR / licensed manufacturer / licensed distributor immediately on becoming aware of a problem, notifies the CEO or in his/her absence his/her designate of the potential recall. Therefore, it is advisable that no recall, regardless of the level, should be undertaken without consultation with the Regulatory Authority and without agreement on the recall strategy. In case of a potential significant health hazard to patients, the HCR / licensed manufacturer / licensed distributor may within 24 hours disseminate information on the recall. This includes precautionary measures to quarantine stock pending the initiation of the recall.

## **9 INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL**

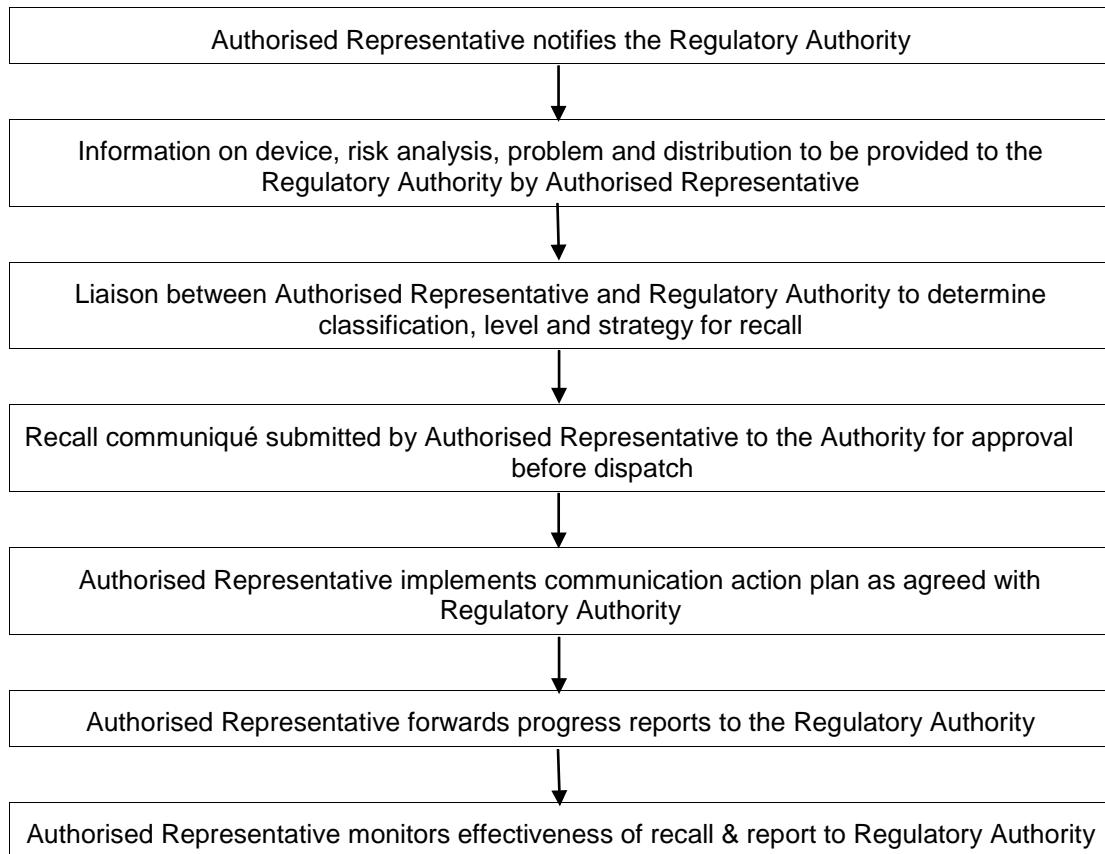
Each recall is a unique exercise. However, in tailoring an appropriate recall strategy, there are a number of factors common to all recalls that need to be considered. Certain information is essential to permit the assessment of the validity of the report of the problem or recall, the potential danger to users and public health and the action appropriate to the situation. The HCR / licensed manufacturer / licensed distributor should gather all relevant information on the recall, which includes the product, its distribution, and action proposed.

In the case of medical devices and IVDs recall provisions must be applied when:

- the medical device does not meet the Essential Principles of Safety and Performance,
- conformity assessment procedures have not been applied to the medical device

The HCR / licensed manufacturer / licensed distributor should make available to the Regulatory Authority all the relevant information regarding the recall on the report form provided as Annex 1. The information required may be included in **Annex 1** but not limited to it only.

Stages of a recall



10 CLASSIFICATION OF RECALLS

Recalls are classified into both the **class** according to the level of health hazard involved (risk to the patient, user or public health) and **type** which denotes the depth or extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc.

Class I or Class II recalls are considered to be urgent safety-related recalls. Class III recalls are considered to be routine non safety-related recalls.

Classification	Description	Examples relating to Medical Devices
Class I (Safety related)	Product defects are defective / dangerous / potentially life-threatening that predictably or probably could result in serious health risk/adverse events or even death and could cause permanent debilitating health issues.	Hot/cold gel packs that contain a toxic substance that could be ingested accidentally by a young child. A software error in a CT scanner that could cause the gantry to rotate in an unintended direction and cause an injury to or the death of a patient. Implantable pacemakers with a defect that results in a loss of pacing output, which for pacemaker-dependent patients may result in death or serious injury. A false result on an IVD test for a medicine with a narrow therapeutic index that could lead to an overdose, causing permanent injury.



## Medical Devices and IVDs

Classification	Description	Examples relating to Medical Devices
Class II (Safety related)	Product defects could cause illness, temporary or medically reversible adverse health problem or mistreatment and the recovery of the patient is likely	<p>Microbial contamination of a surgical lubricant.</p> <p>A software error in a radiation treatment planning tool that could lead to therapy being miscalculated and incorrectly administered.</p> <p>The <i>Instructions for Use</i> for a catheter omits a precaution for certain procedures that could cause complications in its removal.</p> <p>The incorrect combination of metal femoral heads and liners has been supplied to surgeons. If implanted then there is a high risk of accelerated wear and tear.</p> <p>An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment.</p>
Class III (Non-Safety related)	Product defects may not pose a significant hazard to health, but are defective and are unlikely to cause any adverse health reaction, withdrawal may be initiated for other reasons, or which do not comply with the requirements of Act 101 of 1965 in terms of the requirements of printed packaging material, product specification, labeling, etc.	<p>A disinfectant has been mislabelled with an expiry date that predates the actual expiry date.</p> <p>The outer packaging of a consumable medical device indicates a different size to that which is actually in the supplied in the box. It would be obvious to the clinician that the consumable was the incorrect size.</p> <p>An IVD reagent is causing calibration failures towards the end of its shelf life. There is no effect on patient results.</p>

### 10.1 Type A

A type A recall is designed to reach all suppliers of medical devices and IVDs (all distribution points) i.e. wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised users and individual customers or patients through media release (radio, television, regional and national press).

**Action: Recall letter to all distribution points plus media release.**

### 10.2 Type B

A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists and authorised users.

**Action: Recall letter to all distribution points.**

### 10.3 Type C

A type C recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals) this can be achieved by means of a representative calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or recalls letters to arrange for the return of the product could be made.

**Action: Specific telephone calls, recall letters to/representatives calling at distribution points if known where the medical devices or IVDs have been distributed.**

## Medical Devices and IVDs

*NOTE: Decisions on the Class and Type of a recall to be initiated are a matter of the Regulatory Authority in consultation with a holder of the registration certificate / licensed manufacturer/ licensed distributor and shall be based on the evidence and/or expert opinion of the Regulatory Authority and HCR.*

### 11 RECALL LETTER CONTENTS

Recall letters should include factual statements of the reasons for the recall of the product, together with special details that will allow the product to be easily identified.

The text of the recall letter is to be sent to the office of the Inspectorate and Law Enforcement for approval before being dispatched. The letter, which must be sent by post and facilitated e-mail or facsimile, should be dispatched within 24 hours of receiving approval from the Inspectorate and Law Enforcement directorate.

A signed copy of the approved recall letter (or facsimile) to customers is to be sent to the office of the Inspectorate and Law Enforcement. In case of an international distribution of the recalled product the primary manufacturer should immediately inform the HCR / licensed manufacturer / licensed distributor and or endeavour to make information available to the Regulatory Authority.

Recall communication from the HCR / licensed manufacturer / licensed distributor to the distribution chain should be written in accordance with the following directive:

1. Shall be on the company's letterhead and signed by the Authorised Representative or the authorised person.
2. The heading should indicate that it is an **“Urgent Medical Device Recall”** or **“Urgent IVD Medical Device Recall”**.
3. The heading should also indicate the classification and type of the recall.
4. Where applicable the name of product, type and model of medical device, registration number, pack size, batch or lot number(s) or serial numbers(s), expiry date and any other relevant information necessary to allow absolute identification.
5. Nature of the defect (be brief and to the point).
6. Urgency of the action.
7. Reason for the action (reason for recall).
8. Indication of a health risk (this should also state exactly what the product may do if used i.e. non-performance).
9. Provide specific information on what should be done in respect of the recalled medical device or IVD. Method of recovery or product correction, which will be used.
10. Where necessary a follow-up communication shall be sent to those who failed to respond to the initial recall communication.
11. Contact telephone number (preferably toll free) and email address.
12. A request to retain the letter in a prominent position for one month in case stock is in transit (*where applicable*).
13. Where recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals in the province, the letter should include the following:  
*“If any of the recalled stock could have been transferred from your hospital to another, please let that hospital know or alternatively inform our company so that we can make contact with the hospital supplied from your hospital”.*

**NB: The recall communication shall not contain any material that can be viewed as promotional in nature.**

**The letter and the envelope shall indicate in bold red type “MEDICAL DEVICE / IVD MEDICAL DEVICE RECALL” and be marked “URGENT”.**

## **12 MEDIA RELEASE**

In the case of a recall where a media release is indicated, the HCR / licensed manufacturer or licensed distributor and the Regulatory Authority make the text of the media release jointly. Expert advice may also be required.

In the case of a Class I or customer level recalls, where it is necessary to issue a media statement, the text of the media release is developed by the HCR / licensed manufacturer / licensed distributor, in consultation with the Regulatory Authority.

The media release should contain sufficient and relevant detail to uniquely define the product, together with a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the user or client.

A 24-hour access telephone number of the HCR / licensed manufacturer/ licensed distributor should be given for further information. The media release will be issued by the HCR / licensed manufacturer / licensed distributor as agreed with the Regulatory Authority.

In the event that the HCR / licensed manufacturer / licensed distributor refuses to do a media release the Regulatory Authority will release the communication to the media.

**Choice of the daily media** – this should be done in consultation with the Regulatory Authority and consideration should be given to the need to inform all ethnic groups in their language.

### **Recommended text to appear on the media release:**

1. Shall be on the company's letterhead and signed by the Authorised Representative or authorised person.
2. The heading should indicate that it is an “**Urgent Medical Device / IVD Medical Device Recall**”.
3. The heading should also indicate the Classification and Type of the recall.
4. Where applicable the name of product, type and model of medical device, registration number issued by Regulatory Authority, pack size, batch or lot number(s) or serial numbers(s), expiry date and any other relevant information necessary to allow absolute identification.
5. Nature of the defect (be brief and to the point).
6. Urgency of the action.
7. Reason for the action (reason for recall).
8. Indication of a health risk (this should also state exactly what the product may do if used, i.e. details of non-performance).
9. Provide specific information on what should be done in respect of the recalled medical device / IVD. Method of recovery or product correction, which will be used.
10. Contact telephone number (preferably toll free) and email address
11. A request to retain the media release in a prominent position for one month in case stock is in transit (*where applicable*).

**NB The Chief Executive Officer/ designate shall publish the recall details in the form of a notice on the Regulatory Authority website and, where applicable, inform the relevant international authorities**

### **13 POST RECALL PROCEDURES**

The HCR / licensed manufacturer / licensed distributor has a legal responsibility for implementing the recall action, and for ensuring compliance with the recall procedure. At two weeks after the implementation of the recall (or at other **agreed times**) the HCR / licensed manufacturer / licensed distributor is to provide the Regulatory Authority with an interim report on the effectiveness of the recall and within 30 days of the recall having been instituted the Regulatory Authority shall be furnished with a final recall report (as per **Annex 2**).

These reports may include but are not limited to the following:

- 13.1 Details on the investigation into the cause of the defect.
- 13.2 The corrective actions proposed/implemented and the dates of implementation to prevent a recurrence of the problem.
- 13.3 The extent of distribution of the relevant batch / serial number(s) in South Africa as well as to the international market.
- 13.4 The success of the recall i.e. quantity of stock returned, corrected, outstanding, etc.
- 13.5 Confirmation, where applicable (e.g. hospitals, pharmacists, doctors, customers, other international regulatory authorities / holder of distribution authorization in the foreign country), that the recall letter was received.
- 13.6 The method of destruction or disposal of the recalled goods.

These reports establish the effectiveness of the recall and form the basis of the report to the Regulatory Authority. Unless satisfactory reports are received, further recall action may have to be considered.

**NOTE: An additional interim report may be requested even before the 30 days have elapsed.**

### **14 FOLLOW-UP ACTION**

- 14.1 The follow-up action consists of an evaluation on the effectiveness of the recall and an investigation of the reason for the recall and corrective actions taken to prevent a recurrence of the problem.
- 14.2 The Control Officer of the Regulatory Authority shall evaluate the reports received from the recalling site and an assessment made of the effectiveness of the recall action
- 14.3 On completion of a recall or during the process of a recall, the recalling site is requested to provide details of the corrective actions and time lines proposed to prevent a recurrence of the problem which gave rise to the recall.
- 14.4 Where the nature of the problem and appropriate corrective actions are not apparent, investigation and in some cases vigilance and/or quality audits may be necessary.
- 14.5 Apparent follow-up actions will be taken by the Regulatory Authority or Inspectorate and Law Enforcement directorate on behalf of the Regulatory Authority as directed. This might include a review of the technical documentation by the Regulatory Authority and any appropriate action instituted by the Regulatory Authority based on the outcome of the review of the applicable technical information.

### **Medical Devices and IVDs**

14.6 Once the recall has been handled satisfactory, the Regulatory Authority will determine closure of the recall.

### **15 CONTACT DETAILS**

Refer to details on the Regulatory Authority's website, [www.sahpra.org.za](http://www.sahpra.org.za)

### **16 UPDATE HISTORY**

<b>Date</b>	<b>Reason for update</b>	<b>Version &amp; publication</b>
Aug 2015	First publication for comment	v1, Sept 2015
30 November 2015	Due date for comment	
April 2017	Integration of Recall guideline and Adverse event and post-marketing vigilance guideline for medical devices and IVDs into one guideline. Addition of Annexures 1 & 2 for reporting to Regulatory Authority.	v2, Aug 2017
With immediate effect	Date for implementation	
November 2019	Administrative update:	Version 2, November 2019

**ANNEX 1 – Recall Information Medical Device or IVD (INITIAL REPORT to Regulatory Authority)**

<b>Recall Information</b>	<b>Information by the HCR / Licensed manufacturer / Licensed distributor</b>
<b>Origin of report</b>	
1. Name of person reporting the problem	
2. Company reporting the problem	
3. Physical address	
4. Telephone number	
5. Facsimile number	
6. E-mail address	
7. Date of report	
<b>Medical Device / IVD details</b>	
1. Name of product affected	
2. IVD or NON-IVD	
3. Class of Medical Device or IVD	
4. Make, type & model of Medical Device / IVD	
5. Manufacturer of the Medical Device / IVD	
6. Licensed Importer (manufacturer or importer) of the Medical Device / IVD	
7. Regulatory Authority allocated medical device establishment licence number	
8. Holder of Certificate of Registration name, address & contact details	
9. Regulatory Authority allocated registration number	
10. Batch / Lot / Serial number(s) and expiry date (s)	
11. Date manufactured	
12. Date released	
13. Total quantity prior to distribution	
14. Quantity released for distribution prior to the recall	
15. Date of distribution	
16. Local distribution (include list of customers who purchased medical device or IVD & details of customers holding “consigned” or “loaned” or “placed” or “demonstration” medical device or IVD)	
17. International distribution (give full details and quantity)	

**Medical Devices and IVDs**

<b>Nature of defect</b>	<b>Information by the HCR / Licensed manufacturer / Licensed distributor</b>
1. Source of complaint (e.g. patient/ surgeon / user/ hospital / pharmacy / manufacturer, etc.)	
2. Details of complaint	
3. Number of complaints received	
4. Initial date complaint was received	
5. Name and address of any Medical Device or IVD Regulatory Authorities notified	
6. Action taken so far (if any) / Proposed action and its urgency	
7. Type of hazard/health risk and assessment of risk to the user or public health (including clinical safety reports)	
8. Proposed recall classification and level	
9. Other relevant information	
The above information may be provided verbally but should also be confirmed in writing within two working days.	

**ANNEX 2 - Post-recall Information Medical Devices & IVDs / FINAL REPORT to Regulatory Authority**

Post recall information	Information by the HCR / Licensed manufacturer / Licensed distributor
1. Name of product affected	
2. IVD or NON-IVD	
3. Class of Medical Device or IVD	
4. Make, type & model of Medical Device / IVD	
5. Manufacturer of the Medical Device / IVD	
6. Licensed Importer (manufacturer or importer) of the Medical Device / IVD	
7. Regulatory Authority allocated medical device establishment licence number	
8. Holder of Certificate of Registration name, address & contact details	
9. Regulatory Authority allocated registration number	
10. Batch / Lot / Serial number(s) and expiry date (s)	
11. Nature of defect	
12. Action taken (taking into account the area of distribution of recalled medical device or IVD), if exported confirmation from the Regulatory Authority and the holder of the distribution authorisation in the foreign country	
13. Urgency of the action taken	
14. Reason for the action	
15. Indication of the health risk and the reported clinical problems	
16. Steps taken to prevent re-occurrence of the problem	
17. Fate of the recalled product (including the decision taken)	
18. The result of the recall-quantity of stock returned, corrected, outstanding, etc.	
19. Confirmation that customers have received the recall letter (include mailing list)	
20. Copies of all recall correspondence including previous correspondences to Regulatory Authority regarding this recall	