MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

GUIDELINE FOR RECALL / WITHDRAWAL OF MEDICINES, MEDICAL DEVICES AND IVDs

This document has been prepared to serve as a recommendation to applicants regarding the recalls of medicines/medical devices/IVDs, and the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines/medical devices/IVDs. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine/medical device/IVD and may make amendments in keeping with the knowledge which is current at the time of consideration of data which has been submitted regarding any recalls. The MCC is committed to ensure that all medicines/medical devices/IVDs that are registered are of the required quality, safety and efficacy. It is important for applicants to adhere to these requirements.

Version 1 – Implementation	May 2003
Version 2 – Inclusion of name and source of API	March 2007
Version 3 – Dec 2008 update to include the Rapid Alert Notification to PIC/S and a MCC website notice (8), finalization of the recall within 30 days (9), update of the contact details (11), editing of Annex 1 and Annex 2 to remove section on "official use", and general editing of the document.	December 2008
Version 3 due date for comment	28 February 2009
Version 3 Implementation	31 March 2009
Version 4 - Inclusion of information relating to Medical devices and IVD recalls, inclusion of Quality Defect Reporting and change to the contact details	August 2015
Version 4 due date for comment	30 November 2015

DR JC GOUWS
REGISTRAR OF MEDICINES

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1 INTRODUCTION

The guidelines for recall/withdrawal of medicines, medical devices and *In Vitro* Devices (IVDs) is the result of an agreement between the holder of the certificate of registration/parallel importer/distributor of the medicine/medical device/IVDs, and the Department of Health: Medicines Control Council (MCC) in South Africa. Its purpose is to define the action to be taken by the Cluster: Food Control, Pharmaceutical Trade and Product Regulation: Directorate: Inspectorate and Law Enforcement and the holder of the certificate of registration /parallel importer of the medicine/medical device/IVDs, when medicines/medical devices/IVDs for reasons relating to their safety, quality and efficacy/performance are to be removed from the market.

The Registrar of Medicines, the Director and Deputy Director: Inspectorate and Law Enforcement and the Medicines Control Officer(s) are responsible for recall/ withdrawal, and will monitor closely the effectiveness of the holder of the registration certificate/parallel importer's/distributors recall actions and provide a scientific, technical and operational advice.

The holder of a certificate of registration (HCR)/parallel importer/distributor should inform the Registrar of all the quality defects that may result in a recall of a medicine/medical device/IVD and the HCR/parallel importer/distributor together with the medicines regulatory authority may decide if there is a need to recall or not.

Each holder of a certificate of registration (HCR)/parallel importer/distributor should advise the medicines regulatory authority of the names, after hours and telephone numbers of two persons who have authority to discuss and, if necessary, implement a recall.

These guidelines serve to remind the holder of a certificate of registration/parallel importer/distributor that the Medicines Control Council expects them to take full responsibility for medicines/medical devices/IVDs recalls, including follow-up checks to ensure that the recalls are successful and that corrective actions are taken.

Most recalls are conducted on voluntary basis. The MCC can recall medicines/medical devices/IVDs when registration thereof has been cancelled, or when medicines/medical devices/IVDs are sold illegally in South Africa or when the medicines/medical devices/IVDs are no longer of quality, safe, efficacious or lacks performance. If the recalling performance is deemed inadequate the MCC will take appropriate actions to remove the product from sale or use.

2 DEFINITIONS

Recall - means the removal of specific batch/batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety or efficacy.

Withdrawal - means the total withdrawal of a medicinal product from the market

Medicine - means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man: or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

Distributor - means the natural or legal person who imports or exports a medical device or IVD which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to their being placed on the market under the natural or legal person's own name and sells them to a healthcare professional, healthcare institution, wholesaler or the user.

3 Definitions - continued

Medical device - means any instrument, apparatus, implement, machine, appliance, implant, [*in vitro*] reagent for *in vitro* use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

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

Parallel importation - means the importation into the Republic of a medicine/medical device/IVD protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder.

Parallel importer - means a person who parallel imports medicine/medical devices/IVDs into the Republic on authority of a permit issued in terms of regulation 7(3) of the Medicines and Related Substances Control Act, 101 of 1965.

Holder of a certificate of registration - means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine/medical device/IVD, including quality and safety and compliance with conditions of registration.

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 despatched or has not left the direct control of the holder of a certificate of registration/ parallel importer. (Refer regulation 43(1) of the Medicines and Related Substances Act, Act 101 of 1965).

3 PROVISIONS OF THE ACT

3.1 Section 19 (1) of the Medicines and Related Substances Act, Act 101 of 1965 - *No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements. Any person who contravenes provision of this sub-section shall be guilty of an offence.*

3.2 Regulation 43(1) of the Medicines and Related Substances Act, Act 101 of 1965 - *Every medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council with regard to such medicine.*

3 Provisions of the Act - continued

3.3 Regulation 21 of the General Regulations relating to medical Devices and IVDs to the Medicines and Related Substances Act, Act 101 of 1965 -

(1) *Every medical device or IVD shall conform with the essential principles furnished to the Council with a Declaration of Conformity prescribed by regulation 9*

(2) Any proposed deviation from accepted standards and specifications as intended in subregulation (1) shall be submitted to the Council for prior approval.

4 NOTIFICATION/INITIATION OF THE RECALL

The recall of a medicine/medical device/IVD can be initiated as a result of reports referred to the holder of a certificate of registration/parallel importer/distributor or Medicines Regulatory Authority-(MCC) from various sources, e.g. manufacturers, wholesalers, retail and hospital pharmacists, doctors. A report may relate to *inter alia* an adverse drug reaction to a particular batch(es), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, counterfeit including adulterated medicines, faulty medical devices or IVDs, non performance of a medical device or IVD etc.

When initiating a recall, the holder of a certificate of registration / Authorized person should take the following aspects into consideration: the extent of public warnings and the successfulness of the recall.

It is imperative that before or upon initiating a recall, the applicant immediately on becoming aware of a problem, notifies the Registrar of Medicines 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 MCC and without agreement on the recall strategy. However, in case of a potential significant health hazard to patients, during the weekend/public holidays the HCR/parallel importer may within 24 hours disseminate information on the recall. This includes precautionary measures to quarantine stock pending the initiation of the recall.

5 INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL

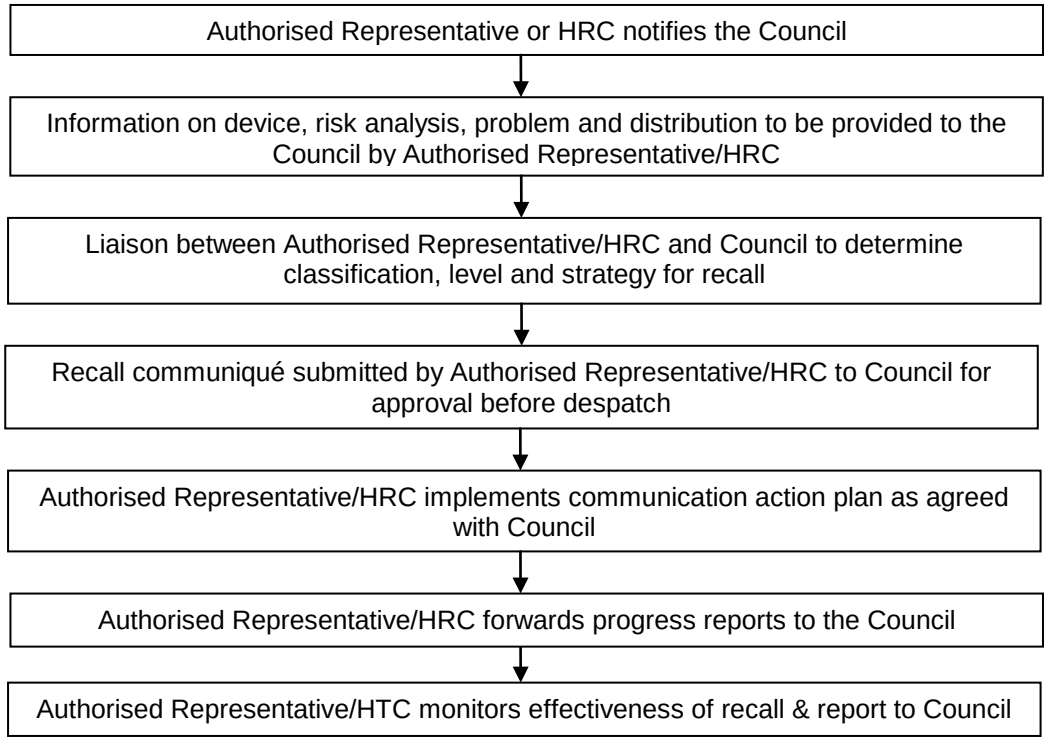
Each recall is a unique exercise. However, in tailoring an appropriate recall strategy, there are a number of factors common to all recalls that need to be considered. Certain information is essential to permit the assessment of the validity of the report of the problem or recall, the potential danger to consumers and the action appropriate to the situation. The HCR/parallel importer/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
- conformity assessment procedures have not been applied to the medical device

The HCR/parallel importer should make available to the MCC all the relevant information regarding the recall on the report form provided as **Annex1**. The information required may be included in **Annex 1** but not limited to it only.

5.1 Stages of a Recall



5.2 Notification / Initiation of the Recall of a Medical Device or IVD

The recall of a medical device or IVD can be initiated as a result of reports referred to the HRC, manufacturer or distributor or the Council from various sources, e.g. international manufacturers, wholesalers, retail and hospital pharmacists, doctors, users. A report may relate to *inter alia* an adverse event relating to a particular batch(es) / lot(s), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, counterfeit including adulterated medical devices etc.

When initiating a recall, the HRC 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 HRC immediately on becoming aware of a problem, notifies the Registrar of Medical Devices & IVDs 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 Council and without agreement on the recall strategy. However, in case of a potential significant health hazard to patients, during the weekend/public holidays the HCR or distributor may within 24 hours disseminate information on the recall. This includes precautionary measures to quarantine stock pending the initiation of the recall.

5.3 Information Required for the Assessment of a Recall

In preparing 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 consumers and the action appropriate to the situation.

5.3 Information Required for the Assessment of a Recall - continued

The HCR should gather all relevant information on the recall, which includes the product, its distribution, and action proposed. The HCR should make available to the Council all the relevant information regarding the recall on the report form provided as Recall Annex1. The information required may be included in Recall Annex 1 but not limited to it only.

6 CLASSIFICATION OF RECALLS

Recalls are classified into both the **class** according to the level of health hazard involved (risk to the patient) 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
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	Microbial contamination of a surgical lubricant A software error in a radiation treatment planning tool that could lead to therapy being miscalculated and incorrectly administered The *Instructions for Use* for a catheter omits a precaution for certain procedures that could cause complications in its removal 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 An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment
Class III (Non-Safety related)	Product defects may not pose a significant hazard to health, but is defective and is 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, labelling, etc.	A disinfectant has been mislabelled with an expiry date that predates the actual expiry date 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 An IVD reagent is causing calibration failures towards the end of its shelf life. There is no effect on patient results

Type A

A type A recall is designed to reach all suppliers of medicines/medical devices/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 prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).

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

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, authorised prescribers and dispensers.

Action: Recall letter to all distribution points.

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 representatives 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 medicines/medical devices/IVDs have been distributed.

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

7 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 despatched. 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 applicant should immediately inform the responsible applicant / distributor and or endeavour to make information available to the regulatory authority in that country.

Recall communication from the holder of the registration certificate / 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 Responsible Pharmacist or authorised person.
2. The heading should indicate that it is an **"Urgent Medicine/Medical/Device/IVD Recall".**
3. The heading should also indicate the classification and type of the recall.
4. Where applicable the name of product, dosage form, strength, registration number, pack size, batch number(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 Recall Letter Contents - continued

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 taken, i.e. side-effects).
9. Provide specific information on what should be done in respect of the recalled medicine/medical device/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 and facsimile return numbers (preferably toll free)
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 "MEDICINE / MEDICAL DEVICE / IVD RECALL" and be marked "URGENT".

8 MEDIA RELEASE

In the case of a recall where a media release is indicated, the holder of a certificate of registration/distributor and the MCC 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 holder of the registration certificate/distributor, in consultation with the MCC.

The MCC may request expect advice before approving any media release statements.

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 consumer/client.

A 24-hour access telephone number of the holder of the registration certificate should be given for further information. The media release will be issued by the holder of the registration certificate/distributor.

In the event that the holder of the registration certificate refuses to do a media release the Medicines Control Council will do the release via the Cluster: Communication of the Department of Health.

Choice of the daily media – this should be done in consultation with the MCC 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 Responsible Pharmacist or authorised person.
2. The heading should indicate that it is an **"Urgent Medicine/Medical Device/IVD Recall".**
3. The heading should also indicate the Classification and Type of the recall.

8 Media Release - continued

4. Where applicable the name of product, dosage form, strength, registration number, pack size, batch number(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 taken, i.e. side-effects).
9. Provide specific information on what should be done in respect of the recalled medicine/medical device/IVD. Method of recovery or product correction, which will be used.
10. Contact telephone number and facsimile return numbers (preferably toll free).
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 Registrar / designate shall publish the recall details in the form of a notice on the MCC website and, where applicable, inform the Pharmaceutical Inspection Co-operation Scheme (PIC/s) of the recall as per the PIC/S (PI 010-2) procedure for handling rapid alerts and recalls from quality defects.

9 POST RECALL PROCEDURES

The HCR/ parallel importer/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/parallel importer/distributor is to provide the MCC with an interim report on the effectiveness of the recall and within 30 days of the recall having been instituted the MCC shall be furnished with a final recall report (as per **Annex 2).**

These reports may include but not limited to the following:

- Details on the investigation into the cause of the defect.
- The corrective actions proposed/implemented and the dates of implementation to prevent a recurrence of the problem.
- The extent of distribution of the relevant batch in South Africa as well as to the international market.
- The success of the recall i.e. quantity of stock returned, corrected, outstanding, etc.
- 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.
- 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 MCC. 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.

FOLLOW - UP ACTION

- 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.

9 Post Recall Procedures - Follow-up action - continued

- The Medicines Control Officer shall evaluate the reports received from the recalling site and an assessment made of the effectiveness of the recall action
- 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.
- Where the nature of the problem and appropriate corrective actions are not apparent, investigation and in some cases Pharmacovigilance and/or Good Manufacturing Practice audits may be necessary.
- Apparent follow-up actions will be taken by the MCC or Inspectorate and Law Enforcement directorate on behalf of the MCC as directed by Council. This might include a review of the medicine dossier by the MCC and any appropriate action instituted by the MCC based on the outcome of the review of the applicable dossier.
- Once the recall has been handled satisfactory, the MCC will determine closure of the recall.

10 REFERENCES

1 Circular 9/98 of the Medicines Control Council.

2 Uniform Recall Procedure for the Therapeutic Goods.

3 PIC/s Procedure for Handling Rapid Alerts and Recalls arising from quality defects, Procedure PI 010-2.

11 CONTACT DETAILS

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12 UPDATE HISTORY

Date	Reason for update	Version & Publication
April 2003	New	2003/1
September 2004	Formatted and edited; correction of Class III	v 1.1
March 2007	Inclusion of API and the source (manufacturer) thereof as recommended by PIC/S assessment team. Replacement of the definition of "stock recovery" with "quarantined stock". Inclusion of requirement that the letter and envelope shall be written in bold red type "MEDICINE RECALL" and be marked "URGENT". Inclusion of submission of the final report within 90 days of medicine recall.	v 2
September 2008	Inclusion of inspections and website notice. Finalization of recall within 30 days. Inclusion of Rapid Alert Notice to PIC/S as per the PIC/S requirement (PI 010-2). Updated contact details.	v 3
August 2015	Inclusion of the Medical Device and IVDs information Inclusion of the Quality Defect Reporting Update of the contact details	v 4, Sept 2015
30 Nov 2015	Due date for comment	

ANNEX 1 – Recall Information *Medicine* (INITIAL REPORT to MCC)

Recall information	**Information by the HCR/Parallel importer**
Origin of report	
1. Name of person/organisation reporting the problem	
2. Company	
3. Physical address	
4. Telephone number	
5. Facsimile number	
6. E-mail address	
7. Date of report	
8. Name of recipient at the MRA/MCC	
Product (medicine) details	
1. Name of product affected	
2. Name of Active Pharmaceutical Ingredient (API)	
3. Source (Manufacturer) of the API	
4. MCC allocated registration number	
5. Dosage form	
6. Strength of the product	
7. Pack size/type	
8. Batch number and expiry date	
9. Manufacturer/holder of the certificate of registration/distributor, address and contact details	
10. Date manufactured	
11. Date released	
12. Total quantity prior to distribution	
13. Quantity released for distribution prior to the recall	
14. Date of distribution	
15. Local distribution (include distribution list)	
16. International distribution (give full details and quantity)	
Nature of defect	
1. Source of complaint (e.g. patient/ hospital/pharmacy/manufacturer, etc)	
2. Details of complaint	
3. Number of complaints received	
4. Initial date complaint was received	

Recall information	**Information by the HCR/Parallel importer**
5. Name and address of any National 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 (including clinical safety reports)	
8. Proposed recall classification and type	
9. Other relevant information	

N.B: The above information could be provided verbally but should also be confirmed in writing within **two working days**

ANNEX 2 – Recall Information Medical Device or IVD (INITIAL REPORT to MCC)

Recall Information	**Information by the HCR**
Origin of report	
1. Name of person/organisation reporting the problem	
2. Company	
3. Physical address	
4. Telephone number	
5. Facsimile number	
6. E-mail address	
7. Date of report	
Medical Device / IVD details	
1. Name of product affected	
2. Make & Model of Medical Device / IVD	
3.Manufacturer of the Medical Device / IVD	
4. Importer of the Medical Device / IVD	
5. Council allocated registration number	
6. Licence Holder name and contact details	
7. Licence Number	
8. Batch / Lot number and expiry date	
9. Manufacturer/holder of the certificate of registration, address and contact details	
10. Date manufactured	
11. Date released	
12. Total quantity prior to distribution	
13. Quantity released for distribution prior to the recall	
14. Date of distribution	
15. Local distribution (include distribution list)	
16. International distribution (give full details and quantity)	
Nature of defect	
1. Source of complaint (e.g. patient/ surgeon/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	

Recall Information	**Information by the HCR**
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 (including clinical safety reports)	
8. Proposed recall classification and level	
9. Other relevant information	

The above information could be provided verbally but should also be confirmed in writing within two working days

ANNEX 3- Post recall information *Medicine* /FINAL REPORT to MCC

Post recall information	**Information by the HCR / Parallel importer**
1. Name of product	
2. Name of Active Pharmaceutical Ingredient(s) (APIs)	
3. Source (Manufacturer) of the APIs	
4. MCC allocated registration number	
5. Dosage form	
6. Strength of product	
7. Pack size/type	
8. Batch number and expiry date	
9. Nature of defect	
10. Action taken (taking into account the area of distribution of recalled medicine), if exported confirmation from the Regulatory Authority and the holder of the distribution authorization in the foreign country	
11. Urgency of the action taken	
12. Reason for the action	
13. Indication of the health risk and the reported clinical problems	
14. Steps taken to prevent re-occurrence of the problem	
15. Fate of the recalled product (including the decision taken)	
16. The result of the recall-quantity of stock returned, corrected, outstanding, etc	
17. Confirmation that customers have received the recall letter (include mailing list)	
18. Copies of all recall correspondence including previous correspondences to MCC regarding this recall.	

ANNEX 4 - Post recall information *Medical Devices and IVDs* /FINAL REPORT to MCC

Post recall information	**Information by the HCR**
1. Name of product affected	
2. Make & Model of Medical Device / IVD	
3.Manufacturer of the Medical Device / IVD	
4. Importer of the Medical Device / IVD	
5. Council allocated registration number	
6. Licence Holder name and contact details	
7. Licence Number	
8. Batch number and expiry date	
9. Nature of defect	
10. 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 authorization in the foreign country	
11. Urgency of the action taken	
12. Reason for the action	
13. Indication of the health risk and the reported clinical problems	
14. Steps taken to prevent re-occurrence of the problem	
15. Fate of the recalled product (including the decision taken)	
16. The result of the recall-quantity of stock returned, corrected, outstanding, etc	
17. Confirmation that customers have received the recall letter (include mailing list)	
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