FORWARD

The Medicines Control Agency (MCA) established by an Act of Parliament and assented to on 24th December 2014 is mandated to regulate the manufacture, import, wholesale, storage, distribution and supply of medicines and related products, and to ensure that all medicines and related products sold and used in the country conform to the required standards of quality, safety and efficacy throughout the product lifecycle in The Gambia.

In pursuance of the Medicines and Related Products Act 2014, Part VIII, MISCELLANEOUS, Section 64 Guidelines herein quoted “the Agency may publish guidelines in connection with matters provided for under this Act for the purpose of giving guidance”, the MCA deems it very essential to develop written Guidelines and Standard Operating Procedures (SOPs) to guide the implementation of the various regulatory functions of MCA in ensuring the safety, efficacy and quality of medicines and related products available to the population.
ACKNOWLEDGEMENTS

The Medicines Control Agency (MCA) wishes to thank the Ministry of Health and Social Welfare, members of the MCA Board and the various institutions for their support. Special thanks is extended to the Global Fund through Action Aid International The Gambia (AAITG) for their financial support in the development of the Quality Assurance Policy and Plan, some regulatory guidelines and SOPs for use by MCA and its stakeholders.

Special thanks is extended to the Technical Working Group and staff of the Medicines Control Agency for their commitment and technical input in the development of this guideline.

Gratitude is extended to key stakeholders including the Directorate of National Pharmaceutical Services, Pharmacy Council, Medical and Dental Association, Pharmaceutical Society of The Gambia, Nurses and Midwives Council, Regional Health Directorates, National Aids and TB Control Programs, National Public Health Laboratory Services and Gambia Standards Bureau for their valuable contributions and participation in the validation of the Quality Assurance Plan, which will ensure that all medicines and related products are of the required quality for their intended use.
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1. LIST OF ABBREVIATIONS AND ACRONYMS

CMS  Central Medical Store
MAH  Marketing Authorisation Holder
MCA  Medicines Control Agency
RMS  Regional Medical Store
WHO  World Health Organization

2. INTRODUCTION

2.1. When medicines or related products are suspected of being potentially harmful to users due to their defective quality, safety or efficacy or lack of performance, they may be subjected to a recall.

2.2. Most recalls are initiated by marketing authorisation holders (MAHs), manufacturers/importers or distributors (suppliers) on a voluntary basis.

2.3. The role of the Medicines Control Agency (MCA) in a recall is to assess the adequacy of the decision on the recall of the product and to monitor the progress and effectiveness of the recall.

2.4. The MCA expects the MAH, manufacturer/importer or distributor to take full responsibility for recalls of medicines or related products, including follow-up checks to ensure that the recalls are successful and that corrective actions are taken.

2.5. If the recalling performance is deemed inadequate the MCA will take appropriate actions to remove the product from sale or use.

2.6. The MCA can also initiate the recall of medicines or related products in addition to 2.1 when registration thereof has been cancelled or when medicines or related products are sold illegally in The Gambia.

2.7. The MCA may instruct the MAH, manufacturer/importer or distributor to recall and dispose of the product according to the circumstances.

2.8. The MCA may alert the public of the product problem.

3. PURPOSE AND SCOPE

3.1. The guideline is intended to ensure that in the event of a necessary recall, the recall operations are carried out appropriately by the MAH, manufacturer/importer or distributor in order to safeguard public health.

3.2. The guideline covers medicines and related products as defined in the Medicines and Related Products Act, 2014.

4. NOTIFICATION/INITIATION OF A RECALL

4.1. The recall can be initiated as a result of reports or complaints on quality, safety or efficacy of a medicine or related product referred to the MAH, manufacturer/importer, distributor or MCA from various sources such as manufacturers, wholesalers, retailers and hospital pharmacies,
research institutes, medical practitioners, dentists, patients, foreign regulatory authorities and World Health Organization (WHO).

4.2. A report may relate to an adverse drug reaction to a particular batch(es), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, substandard or falsified product including adulterated medicines, or faulty related products such as medical devices or non-performance of a medical device, etc.

4.3. A recall might also be initiated as a result of analysis and testing of samples of medicines or related products by the manufacturers or MCA. Recall of medicines or related products manufactured outside of The Gambia might be initiated by the MCA or foreign regulatory authorities, or from information received directly from such authorities.

4.4. It is imperative that before or upon initiating a recall, the applicant immediately (within 24 hours) on becoming aware of a problem, notifies the MCA of the potential recall in writing by e.g. email or fax. Therefore it is advisable that no recall, regardless of the level, should be undertaken without consultation with the MCA and without agreement on the recall strategy.

4.5. However, in case of a potential significant health hazard to patients, during the weekend/public holidays the MAH, manufacturer/importer or distributor may within 24 hours disseminate information on the recall. This includes precautionary measures to quarantine stock pending the initiation of the recall.

4.6. The MAH, manufacturer/importer or distributor shall not wait to notify the MCA until ALL applicable information is prepared and assembled. This immediate notification is necessary to allow the MCA to review and comment on the written notification and to offer guidance and assistance in the recall process.

5. INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL

5.1. Each recall is a unique exercise. There are a number of factors common to all recalls that need to be considered in tailoring an appropriate recall strategy. These include the nature of the deficiency in the product, the incidence of complaints, the potential danger to consumers and public safety, distribution networks, recovery procedures, resources for corrective action appropriate to the situation and availability of alternative products.

5.2. The MAH, manufacturer/importer or distributor should gather all relevant information on the recall, which includes the product, its distribution channels, and action proposed.

5.3. When the need for recall has been established, additional information is required so that an appropriate recall strategy may be devised. A summary of the information required is provided in Section 5.8.
5.4. The MAH, manufacturer/importer or distributor should make available to the MCA all the relevant information regarding the recall on the **Recall Information Form**. The information required may be included in the form but not limited to it only.

5.5. In determining the recall strategy, the MAH, manufacturer/importer or distributor should consider the factors which may affect the duration of the recall action and should inform the MCA.

5.6. When the required information is available, the appropriate strategy should be proposed to the MCA. The proposed recall strategy should be agreed by the MCA before implementation (see Section 4.4). The actual implementation of the recall includes use of the basic steps which are summarized in Appendix 1 and these will be common to all strategies.

5.7. The recall should be completed by the date as agreed with the MCA.

5.8. In the recall strategy, the MAH, manufacturer/importer or distributor should mention the following:

- Indicate the proposed level in the distribution chain to which the recall is extending (see type of recall below), if the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;
- In case of **consumer level** recall, additional information should be mentioned:
  - Indicate the location of recall spots for consumers (preferably not less than 7 recall spots covering the seven health regions), their operation time and duration as appropriate;
  - Indicate the hotlines number(s) for enquiry and the corresponding operating hours;
- Indicate the method of recall notification (e.g. mail, phone, facsimile, email);
- Indicate how the message of recall will be delivered to customers e.g. press release or recall letters, etc;
- If the MAH, manufacturer/importer or distributor has a website, it should be considered posting the recall notification on it as an additional method of recall notification;
- Report on what have the customers been instructed to do with the recalled product;
- If products are to be returned, explain the mechanism of the process;
- Explain if the recall will create a market shortage that will impact on the consumer;
- Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to manufacturer;
- Inform MCA before product destruction, the proposed method of destruction would be reviewed and MCA to witness the destruction exercise. For details on destruction refer to the MCA guideline for Safe Disposal of Medicines and Related Products.
6. **CLASSIFICATION AND TYPES (LEVELS) OF RECALLS**

**Classes**

6.1. 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.

6.2. Class I or Class II recalls are considered to be urgent safety-related recalls and must be reported to the MCA immediately for further evaluation and investigation.

6.3. Class III recalls are considered to be non-safety related recalls.

6.4. Each recall is a unique exercise and there may be occasions when the scope of a recall can be narrowed to particular customer groups. Expert advice might be sought where the nature of the hazard or its significance is not clear.

6.5. Decisions on the Class and Type (Level) of a recall to be initiated are a matter of the MCA in consultation with the MAH, manufacturer/importer or distributor and shall be based on the evidence and/or expert opinion of the MCA.

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<thead>
<tr>
<th>Classification</th>
<th>Description</th>
<th>Examples</th>
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| **Class I** (Safety related) | Product defects are dangerous/ potentially life-threatening that predictably or probably could result in serious health risk/adverse reactions or even death and could cause permanent debilitating health issues. | • Wrong Product (label and contents are different products)  
• Correct product but wrong strength, with serious medical consequences  
• Microbial contamination of sterile injection or ophthalmic product  
• Chemical contamination with serious medical consequences  
• Mix up of some products („rogues“) with more than one container involved  
• Wrong active ingredient in a multi-component product with serious medical consequences |
| **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 | • Mislabelling e.g. wrong or missing text or figures  
• Missing or incorrect information- leaflets or inserts  
• Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences  
• Chemical/physical contamination (significant impurities, cross contamination, particulates)  
• Mix up of products in containers („rogues“)  
• Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)  
• Insecure closure with serious medical consequences (e.g. cytotoxics, child resistant containers, potent products) |
Class III  
(Non-Safety  
related)

| 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 regulatory requirements in terms of printed packaging material, product specification, labelling, etc. | • Faulty packaging e.g. wrong or missing batch number or expiry date  
• Faulty closure  
• Contamination- microbial spoilage, dirt or detritus, particulate matter |

Types (Level)

6.6. In determining the recall type (level or depth), the principal factors to be considered are the significance of the hazard (if any), the channels by which the medicines or related products have been distributed, and the level to which distribution has taken place.

6.7. There are three types of recalls, A, B and C.

Type A

6.8. A type A recall is designed to reach all suppliers of medicines or related products (all distribution points) i.e. hospitals, health centres, clinics (public as well as private), wholesalers, central medical store, regional medical stores, retailers and individual customers or patients through press release (radio, television, print media).

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

Type B

6.9. A type B recall is designed to reach hospitals, health centres, clinics (public as well as private), wholesalers, central medical store (CMS), regional medical stores (RMS), and retailers.

Action: Recall letter to all distribution points.

Type C

6.10. A type C recall is designed to reach wholesale level, CMS, RMS, hospitals and clinics which can be reached by means of a representative calling on.

Action: Recall letters to representatives at distribution points where the medicines or related product have been distributed.

7. RECALL LETTERS AND PRESS RELEASE

Letters

7.1. 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.

7.2. The text of the recall letter is to be sent to the MCA for approval before being despatched.

7.3. The approved recall letter may be sent within 24 hours of receiving approval and a signed copy of the approved recall letter is to be sent to the MCA.
7.4. If safety to the public is involved and distribution is limited, the MAH, manufacturer/importer or distributor may contact the clients of the information listed below by telephone and followed by a recall letter.

7.5. Recall communication from the MAH, manufacturer/importer or distributor to the distribution chain should be written in accordance with the following:

- Should be on the company’s letterhead and signed by the Responsible Pharmacist or authorised person.
- The subject of the letter should indicate that it is an “Urgent Medicine Recall” or “Urgent Related Product Recall”.
- The heading should also indicate the classification and type of the recall.
- Name of the product and manufacturer and where applicable the dosage form, strength, registration number, pack size, batch number(s), expiry date and any other relevant information necessary to allow absolute identification.
- Nature of the defect (be brief and to the point).
- Urgency of the action.
- Reason for the recall.
- Indication of a health risk (this should also state exactly what the product may do if taken, i.e. adverse reactions). It should be made clear that further distribution or use of the product should cease immediately.
- Provide specific information on what should be done in respect of the recalled medicine or related product and method of recovery or product correction, which will be used.
- Contact telephone number and facsimile return numbers or email addresses.
- There should be a request for a written response to confirm receipt and understanding of the action to be taken.
- Where necessary a follow-up communication shall be sent to those who failed to respond to the initial recall communication.
- Where recalled stock has been distributed to a limited number of facilities and the recall letter is not to be sent to all facilities, the letter should include the following:

“If any of the recalled stock could have been transferred from your facility to another, please let that facility know or alternatively inform us so that we can make contact with the facility supplied from your facility”.

Press Release

7.6. Rapid alert to public is usually reserved for hazards classified as Class I, and where appropriate Class II, or situation where other means for controlling the hazard appear inadequate. Rapid alert to public may be issued through appropriate channels which may include press release.
7.7. In the case of a recall where a press release is indicated, jointly the MAH, manufacturer/importer or distributor and the MCA make the text of the press release.

7.8. The press release should contain sufficient and relevant details 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.

7.9. The media release will be issued by the MAH, manufacturer/importer or distributor and an access telephone number of the MAH, manufacturer/importer or distributor should be given for further information.

7.10. In the event that the MAH, manufacturer/importer or distributor refuses to do a press release the MCA will do the release.

7.11. The choice of the media should be done in consultation with the MCA and consideration should be given to the need to inform the public in the major local languages.

7.12. The MCA will publish the recall details in the form of a notice on the MCA website.

8. **RESPONSIBILITIES OF MAH, MANUFACTURER/IMPORTER OR DISTRIBUTOR**

8.1. MAH, manufacturer/importer or distributor are responsible to maintain records and establish procedures which will facilitate a recall and taking the prime responsibility for implementing a recall where it is necessary including the costs.

8.2. The complete records pertaining to distribution should be retained for one year after the expiry date of each batch (see MCA Guideline for Storage and Distribution of Medicines and Related Products).

8.3. The MAH, manufacturer/importer or distributor as well as the MCA should retain records of problem reports received about each product. Problem reports should be evaluated by competent personnel and appropriate action taken. The evaluation of each report and the action taken should be shown in the records.

8.4. Recalled medicines should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

8.5. The particular storage conditions applicable to medicines which are subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question (see MCA Guideline for Storage and Distribution of Medicines and Related Products).
9. **POST RECALL PROCEDURES**

9.1. Within two weeks of the recall having been instituted the MCA shall be furnished by the MAH, manufacturer/importer or distributor with a final report on the effectiveness of the recall on the **Recall Report Form**.

9.2. The report should 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 The Gambia as well as outside.
- The success of the recall i.e. quantity of stock returned, corrected, outstanding, etc.
- Confirmation, where applicable, (e.g. wholesalers, health facilities, retailers customers, other international regulatory authorities) that the recall letter was received.
- The method of disposal of the recalled goods.

9.3. The MAH, manufacturer/importer or distributor should report to the MCA with relevant explanation and obtain its approval if the final report cannot be submitted within two weeks after commencing of the recall.

9.4. The report establishes the effectiveness of the recall. Unless satisfactory report is received, further recall action may have to be considered.

10. **EVALUATION OF THE RECALL**

10.1. The evaluation consists of a check on the effectiveness of the recall and an investigation of the reason for the recall as well as the remedial action taken to prevent a recurrence of the problem.

10.2. The MCA shall evaluate the reports received from the recalling site and an assessment made of the effectiveness of the recall action. In some cases the MCA may contact a percentage of customers in the distribution list as a means of assuring the MAH, manufacturer/importer or distributor is carrying out its recall responsibilities.

10.3. The MAH, manufacturer/importer or distributor shall identify the root cause of the problem and implement the corrective and preventive actions accordingly.

10.4. On completion of a recall or during the process of a recall, the MAH, manufacturer/importer or distributor 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.

10.5. Where the nature of the problem and appropriate corrective actions are not apparent, investigation and in some cases Pharmacovigilance and/or Good Manufacturing Practice inspections or audits may be necessary (refer to MCA Guidelines for National Pharmacovigilance System and MCA Guideline for Inspections by the Medicines Control Agency).
10.6. Apparent follow-up actions will be taken by the MCA. This might include a review of the medicine dossier by the MCA and any appropriate action instituted by the MCA based on the outcome of the review of the applicable dossier.

10.7. Once the recall has been handled satisfactorily, the MCA will determine closure of the recall.

10.8. Where a recall is initiated following a report submitted by a foreign regulatory authority, the reporter should be provided with an outline of the results of investigation and a summary of the recall.

11. **REINSTATMENT OF SUPPLY**

11.1. The quality of the products shall conform to specific requirements before resuming the supply to public. The MAH, manufacturer/importer or distributor must seek approval from MCA before reinstatement of the medicines previously recalled.

11.2. After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the MAH, manufacturer/importer or distributor shall submit analytical report(s) of the new batch tested to the MCA as a proof of product quality that will be evaluated by the MCA.

11.3. After evaluation the MCA will inform the MAH, manufacturer/importer or distributor whether the submitted reports are satisfactory.

11.4. The MCA may take samples of the first three batches of the product for testing and will inform the MAH, manufacturer/importer or distributor whether the analytical test was satisfactory.

12. **FINAL PROVISIONS**

12.1. This guideline is the first version published by the MCA.

12.2. This guideline will become effective on 01 January 2018.

12.3. The guideline will be reviewed within 2 years of becoming effective.

13. **DOCUMENT HISTORY**

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<th>Version No</th>
<th>Issue Date</th>
<th>Reasons for Change</th>
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<td>1.0</td>
<td>13 Dec 17</td>
<td>New document</td>
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14. DEFINITION OF TERMS

The definitions provided below apply to the words and phrases used in the MCA guidelines. Although an effort has been made to use standard definitions as far as possible, minor alterations have been made in some cases.

Adverse drug reaction:
A noxious and unintended response to a medicine

Batch (or Lot):
A defined quantity of products processed in a one process or series of processes so that it is expected to be homogeneous.

Batch number (or Lot number):
A distinctive combination of numbers and/or letters which specifically identifies a batch

Container
The material employed in the packaging of a medicine; containers include primary, secondary and transportation containers

Contamination:
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a medicine or related product during handling, sampling, packaging or repackaging, storage or transportation

Distribution
The holding, storing, selling, supplying, importing, exporting, or movement of medicines or related products, with the exception of the dispensing or providing medicines directly to a patient or his/her caregiver

Efficacy:
The measurement of a medicine's desired effect under ideal conditions, such as in a clinical trial

Expiry Date:
The date given on the individual container (usually on the label) of the medicine or related product up to and including the date on which the product is expected to remain within specifications, if stored correctly; it is established for each batch by adding the shelf life to the date of manufacture and is determined by using stability studies

Falsified medicine:
This is a fake medicine that passes itself off as real, authorised medicine

Good Manufacturing Practice (GMP):
A code of standard practices concerning the production, processing, packing, release and holding of a medicine which ensure that medicines are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorisation
**Guideline:**
A document providing guidance on the scientific or regulatory aspects of medicines; MCA expects that justification is provided for any deviations and is approved by MCA

**Importation:**
The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone)

**Inspection:**
The act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications

**Labelling:**
Information on the primary or secondary packaging of a medicine

**Manufacture:**
Includes the operations involved in the production, preparation, processing, refining, transformation, packaging, repackaging and labelling of medicines or related products

**Manufacturer:**
A company or entity that carries out operations such as production, packaging, repackaging, labelling and relabelling of medicines or related products

**Marketing authorisation (or Registration):**
A legal document issued by the MCA for the purpose of marketing or free distribution of a product in The Gambia after evaluation for safety, efficacy and quality.
It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization.
Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

**Marketing authorisation holder (MAH):**
The manufacturer or other legal entity in whose name the marketing authorization for a product has been granted and is responsible for all aspects of the product and compliance with the conditions of marketing authorisation to market a medicine in one or several countries
**Medicine:**
A substance or mixture of substances prepared, sold or represented for use in
the diagnosis, treatment, mitigation or prevention of disease, disorder of
abnormal physical state or the symptoms of it, in man or animal, restoring,
correcting or modifying organic functions in man or animal, including nutritional
supplements or herbal medicines

**Package leaflet (or Patient information leaflet (PIL)):**
The leaflet in every pack of medicine that contains information on the medicine
for end-users, such as patients and animal owners

**Packaging (or Packing):**
All operations, including filling and labelling, which a bulk product has to undergo
in order to become a finished product

**Packaging material:**
Any material employed in the packaging of a medicine, excluding any outer
packaging used for transportation or shipment; packaging materials are referred
to as primary (immediate) or secondary (outer) according to whether or not they
are intended to be in direct contact with the product

**Pharmacist:**
A pharmacist registered under the Pharmacy Council Act 2014, holding a current
certificate of registration

**Pharmacovigilance (PV):**
The science and activities relating to the detection, assessment, understanding
and prevention of adverse effects or any other medicine related problem (WHO).

**Primary container/packaging (or Immediate packaging):**
Container that is in direct contact with the product

**Product:**
Refers to a medicine and/or a related product

**Product information:**
Documents providing officially approved information for healthcare professionals
and patients on a medicine; the product information includes the summary of
product characteristics, package leaflet and labelling

**Quarantine:**
The status of a medicine or related product isolated physically or by other
effective means while a decision is awaited on their release, rejection or
reprocessing

**Recall:**
The removal of specific batch/batches of a medicine or related product from the
market for reasons relating to deficiencies in the quality, safety or efficacy
Related product:
An article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal

Repackaging:
The act of taking a medicine from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the medicine

Secondary container/packaging (or Outer packaging):
Container that is not in direct contact with the medicine

Shelf-life:
The period of time during which a medicine or related product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf-life is used to establish the expiry date of each batch

Storage:
The storing of medicines and related products from manufacturing up to their point of use

Summary of product characteristics (SmPC):
A document describing the properties and the officially approved conditions of use of a medicine; summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively

Supplier:
A person or entity engaged in the activity of providing products and/or services; this may be a manufacturer, importer, wholesaler or distributor
Appendix 1: Flow Chart on Recall Stages

1. Receipt of Product Problem
2. Notification to the MCA
3. Initiation of a Recall
4. Information Required by MCA for Assessment of
5. Assessment of Recall by MCA
6. Agreement on Recall Strategy
7. Recall according to Class and Type
8. Progress of Recall and Final Report
9. Evaluation of the Recall
10. Closure of Recall