These guidelines are meant to provide assistance to the pharmaceutical industry and health care professionals on how to comply with the governing statutes and regulations. They also provide assistance to the secretariat of the Namibia Medicines Regulatory Council (NMRC) on how NMRC’s mandates and objectives should be implemented in a manner that is fair, consistent and effective.

NMRC reserves the right to request information or material or define conditions not specifically described in these guidelines, in order to allow the NMRC to adequately assess the safety, efficacy or quality of a medicinal product. NMRC is committed to ensuring that such requests are justifiable and that decisions are evidence-based.
1. INTRODUCTION

The guidelines for the recall or withdrawal of medicines are the result of an agreement between the Holder of the Certificate of Registration (HCR) of the medicine and the Namibia Medicines Regulatory Council (NMRC). Their purpose is to define the action to be taken by NMRC and the holder of the certificate of registration of the medicine, when medicines, for reasons relating to their safety, quality and/or efficacy, are to be removed from the market.

The NMRC is responsible for recall/withdrawal, and will closely monitor the effectiveness of the holder of the certificate of registration recall/withdrawal actions and provide a scientific, technical and operational advice. Each holder of a certificate of registration (HCR)/wholesaler/distributor/importer must advise the NMRC of the names, and the afterhours telephone numbers of two persons who have authority to discuss and, if necessary, implement a product recall. These guidelines serve to remind the holder of a certificate of registration that the NMRC requires them to take full responsibility for medicines recalls or withdrawals, including follow-up checks to ensure that the recalls or withdrawals are successful and that corrective actions are taken.

Most product recalls or withdrawals are conducted on voluntary basis. The NMRC can recall or withdraw medicines when the registration thereof has been cancelled, or when medicines are sold illegally in Namibia. If the performance of the recalling or withdrawing exercise is deemed inadequate, NMRC will take appropriate actions to effectively remove the product from sale, distribution or use, and the cost of this exercise will be borne by the person or institution having responsibility for the product/s being recalled or withdrawn.

2. RESPONSIBILITY:

2.1 NMRC and its Secretariat
2.2 Holder of certificate of registration
2.3 Holders of import / export permits

3. DEFINITIONS:

3.1 Recall: means the removal of a specific batch / batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety and/or efficacy.
3.2 Withdrawal: means the total removal of a medicinal product from the market.
3.3 Holder of a certificate of registration (HCR): means a person or entity in whose name a certificate of registration of a medicinal product has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration.
3.4 Recall letter: means a formal, written communication from the NMRC to a HCR or from a HCR to the distribution chain directing a product recall
3.5 Holder of import / export licence: means a holder of a licenee to import / export medicines or scheduled substances in terms of section 31(5) (c) of the Medicines and Related Substances Control Act (Act 13 of 2003).
4. CLASSIFICATION OF PRODUCT RECALLS:

Product recalls are classified into the class according to the level of health hazards involved (risk to patient) and type, which denotes the depth or extent to which the product should be recalled from the distribution chain.

Class I
Class I is for defective / dangerous / potentially life-threatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

Examples:
1. Wrong product (label and contents are different products).
2. Correct product but wrong strength, with serious medical consequences.
3. Microbial contamination of sterile injectable or ophthalmic product.
4. Chemical contamination with serious medical consequences.
5. Mix up of some products with more than one container involved.
6. Wrong active ingredient in a multi-component product with serious medical consequences.

Class II
For medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Examples:
1. Mislabelling: e.g. wrong or missing text or figures.
2. Missing or incorrect information - leaflets or inserts.
3. Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences.
4. Chemical/physical contamination (significant impurities, cross-contamination, particulates).
5. Mix up of products in containers (“rogues”).
6. Non-compliance with specification (e.g. assay, stability, fill/weight).
7. Insecure closure with serious medical consequences (e.g. cytotoxics, child-resistant containers, potent products)

Class III
For medicines that are defective but are unlikely to cause a problem; or which do not comply with the requirements of the Medicines and Related Substances Control Act (Act 13 of 2003) in terms of the requirements printed packaging material, product specifications, labeling, etc.

Type A

This type of product recall is designed to reach all suppliers of medicines (all distribution points) i.e. wholesalers throughout the country and those in charge of hospital services in various regions (private as well as state), retail outlets, doctors, nurses, pharmacists, authorized prescribers, dispensers and individual customers or patients through media release (radio, television, national press etc)
The product recall letter should be forwarded to distribution points plus through media release.

Type B

This type of recall is designed to reach wholesalers throughout the country, heads of hospital services, retail outlets, doctors, nurses, pharmacists, authorized prescribers and dispensers

The product recall letter should be forwarded to distribution points.

Type C

This type of recall is designed for specific retail outlets where the product in question has been distributed. Specific telephone calls, recall letters to or representative calling at distribution points to arrange for a return of the product.

The decision on the class and type of a recall to be initiated is made by NMRC in consultation with a holder of the certificate of registration (HCR). In the event of a greater urgency e.g. after hours or over weekends, the decision to recall can be made by the HCR.

5. THE PRODUCT RECALL LETTER

The product recall communication from HCR to the distribution chain should be written in accordance with following directive:

- Shall be on the company letterhead and signed by any authorized person / responsible pharmacist.
- The heading should indicate that it is an “Urgent Medicine Recall”.
- Name of the product, dosage form, strength, registration number, package size, batch number(s), expiry date and any other relevant information necessary to allow absolute identification.
- Nature of the defect (brief and to the point)
- Urgency of the action.
- Reason for the action (recall)
- Indication of a health risk (should indicate clearly what the product may do if taken i.e. adverse effects).
- Provide specific information on what should be done in respect of the recalled medicine. Method of recovery or product correction which will be used.
- Where necessary, a follow-up communication shall be sent to those who failed to respond to the initial recall communication.
- A request to retain the letter in a prominent position for one month while the stock is in transit (where applicable).
- Where a 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 region, the letter should include the following “ if any of the recalled stock could have been transferred from your hospital to another hospital or other health facility, please let that hospital or other health facility know..."
facility know or alternatively inform our company so that we can make contact with the hospital or other health facility that was supplied by your hospital”

6. MEDIA RELEASE

In case of a product recall where media release is indicated, the HCR and the NMRC shall jointly compile the text of the media release.

The media release should contain sufficient information to describe the product and a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the consumer or client.

The media release will be issued by the HCR. In the event that the holder of the certificate of registration refuses to process and issue a media release, the NMRC will issue the release. The cost of the media release shall be borne by the holder of the certificate of registration.

7. POST PRODUCT RECALL PROCEDURES

The NMRC shall be furnished with a final reconciliation report within 30 days of the recall of medicinal product having been instituted. An interim report may be requested even before the 30 days have elapsed.

8. REFERENCES

4.1 SADC Guidelines for recall / withdrawal of medicines, April 2007
4.2 Circular no 01/10/2006 – Ministry of Health and Social Services, Namibia
4.4 European Medicines Agency: Classification of Batch Recalls for Quality Defects