MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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VETERINARY DRUG RECALLS

This document has been prepared to serve as a recommendation to applicants regarding the recalls of veterinary medicines, and the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine 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 that are registered are of the required quality, safety and efficacy. It is important for applicants to adhere to these requirements.

REGISTRAR OF MEDICINES
MS M.P. MATSOSO

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WITHDRAWAL OR RECALL OF VETERINARY PHARMACEUTICAL PRODUCTS BY THE APPLICANT

1.DEFINITIONS

Withdrawal: is the removal or total withdrawal of the product from the market.

Recall: is the removal from the market of a specific batch or batches of product.

Patient: is the animal patient/s to which the veterinary medicine is administered.

Client: is the owner of the patient treated by the veterinarian.

End – user: is the person administering the veterinary medicine to the patient be this the veterinarian or the veterinarian's *bona fide* client .

Consumer: is a person ingesting foods of animal origin. The relevant issue here is potentially harmful veterinary drug residues in animal products.

2. REASONS FOR A RECALL

An applicant may be required to recall a particular batch or batches of a veterinary product from the market due to:

- a report of an adverse drug reaction to a particular batch of a product by the end – user, patient or consumer,
- product deficiencies identified as result of ongoing stability studies,
- technical complaints experienced regarding the printed packaging material, contamination, mislabelling, counterfeit, etc or
- when requested or instructed by the Medicines Control Council.

3. PROCEDURE

3.1.The following procedure provides some guidelines on the withdrawal or recall of a defective or possible harmful veterinary medicine from the market. These guidelines serve to remind the Pharmaceutical Industry that the Council expects the applicant to take full responsibility for product recalls, including follow-up checks to ensure that the recalls are successful. When initiating a recall, the applicant should consider the following aspects: the extent of public warnings and the success of the recall.

3.2All recalls shall be categorized into three classes according to the level of health hazard involved (risk to the patient / end – user / consumer). On determining the level of hazard to the patients' / end – users' / consumer's health the depth or extent to which a product should be recalled from the distribution chain level could also be categorized into one of three types of recalls.

CLASS OF RECALLS

Class I

Class I recalls are for dangerous or defective products that predictably or probably could cause serious adverse health consequences or death to the patient / end - user / consumer.

Class II

Class II recalls are for products that possibly could cause a temporary or medically reversible adverse health problem.

Class III

Class III recalls are for defective products that are unlikely to cause any adverse health reaction or which do not comply with the requirements of Act 101 of 1965 in terms of the requirements for printed packaging material, product specifications, labelling etc.

TYPES OF RECALL (i.e. the depth of the recall).

Type A

A Type A recall is designed to reach all the suppliers of veterinary medicines (all distribution points) i.e. wholesalers throughout the country, distributors, veterinary medicine suppliers, private and academic veterinary hospitals and clinics, Animal Welfare Organisations, pharmacists working in private and academic veterinary clinics / hospitals, veterinarians, veterinary nurses, Animal Welfare Assistants, individual clients and consumers through press release (radio, television, regional and national press). [Recall letter to all distribution points plus press release]

Type B

A Type B recall is designed to reach wholesalers throughout the country, private and academic veterinary hospitals and clinics, veterinarians, veterinary nurses, pharmacists working in private and academic veterinary clinics / hospitals, [Recall letter to all distribution points]

Type C

A Type C recall is designed to reach wholesale level and other distribution points (e.g. veterinarians, private and academic veterinary clinics/hospitals) This could be achieved by means of representatives calling on wholesalers. If it is known where the product in question had been distributed, specific telephone calls or recall letters to arrange for the return of the product must be made.

3.3 The aforementioned information implies that a specific recall initiated could be identified as a specific Class combined with a specific Type Recall e.g. Class I, Type C for a product that could result in a possible health hazard to the patient where the product was distributed to only one veterinarian for the treatment of a few specific patients etc.

TYPE	A	B	C
CLASS			
I			X
II			
III			

3.4 Note that the Class and Type of recall to be initiated shall be decided by the Medicines Control Council, Registrar of Medicine or the Deputy-Director: Medicines Control in consultation with the Applicant and shall be as far as possible based on documented evidence and/or expert opinion of the Council and Applicant. In the event of greater urgency e.g. after hours or over weekends, the decision to recall a veterinary product from the market should be initiated by the applicant concerned following the abovementioned guidelines.

3.5 Should the performance of the applicant responsible for the recall be deemed to be inadequate, the Medicines Control Council may take appropriate action to remove the veterinary product from sale or use. An applicant's recall does not preclude enforcement actions being taken by the regulatory authority as deemed appropriate, either during, or following the completion of the recall.

4. INFORMATION TO BE SUBMITTED

The basic information that would be required by the Registrar for the decision on the status of the initiated recall would include the following:

1. The name and strength of the veterinary product to be recalled, pack size, batch/lot number, any means of identification, and the registration number of the product.

2. The total quantity of the recalled veterinary product batch originally in the applicants possession prior to the distribution.

3. The date distribution began of the recalled veterinary product.

4. Area of distribution of the recalled veterinary product and, if exported, the country to where it was exported.

5. The total quantity of the recalled veterinary product that had been distributed up to the time of the recall.

6. Suggested action to be taken and it's urgency.

7. Indication of the health risk to the patient/end – user / consumer together with reasons.

This Information could be provided verbally but it should be confirmed in writing within 3 days.

5. RECALL COMMUNICATION GUIDELINES

The Recall communication from the Applicant to the distribution chain should be written in accordance with the following guidelines;

1. Should be on a letterhead from the Applicant of the product and signed by the Managing Director (or Responsible Pharmacist in terms of the Pharmacy Amendment Bill when proclaimed);

2. State the name, strength and registration number of veterinary product, pack size, and any other pertinent descriptive information of the product;

3. Nature of the defect (be brief and to the point);

4. Urgency of the action;

5. Reason for the action (must accurately describe the problem);

6. Indication of the health risk; and

7. Provide specific instructions on what should be done in respect of the recalled veterinary product.

8. The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may distract from the message. Where necessary, follow-up communication should be sent to those who fail to respond to the initial recall communication.

6. POST RECALL PROCEDURES

The Medicines Control Council must be furnished with a written report within 30 days of the recall or withdrawal having been instituted. The report shall contain the following;

1. Name of the product;
2. Strength of the product;
3. Registration number
4. Pack size and Batch/lot number
5 Nature of the defect;
6. Action taken (taking into account the area of the distribution of the recalled product), and if exported confirmation of the notification of the Regulatory Authority and Applicant for the product in the country of export;
7. Urgency of the action taken;
8. Reason for the action;
9. Indication of the health risk to the patient/end–user/consumer and reported clinical problems;
10. Copies of all the recall correspondence including reference to previous correspondence to the council regarding the recall;
11. Steps taken to prevent a re-occurrence of the problem and
12. Fate of the recalled product (including the decision taken).