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GUIDELINES FOR DISPOSAL OF PHARMACEUTICAL WASTES SUPERVISED BY NATIONAL DRUG AUTHORITY

BACKGROUND

National Drug authority is mandated by the act of Parliament “Chapter 206” 2000 Edition to regulate human Veterinary Medicines and other health Care products in Uganda for Quality, Safety and efficiency.

Expired pharmaceutical products and other substandard pharmaceutical products therefore present a serious threat to public health and to the environment. Their elimination from the public and subsequent disposal is embedded in NDAs mandate of ensuring that only safe, efficacious and quality drugs are availed to the entire population of Uganda.

It is against this background that these guidelines have been drawn. Their adoption and implementation will help improve quality of drugs on the market and public institutions and prevent access to expired and substandard drugs.

These guidelines therefore provide a practical advice of the safe disposal of unsuitable pharmaceutical products and suggest feasible low-cost disposal options which will minimize risk to the public health and also minimize environmental pollution.

DRUG DISPOSAL RECOMMENDATION

1. SORTING

The appropriate safe disposal method recommended will depend upon the pharmaceutical form of the drugs; therefore, the first step is to sort the materials by form i.e. type e.g. Tablets, syrups, rubbers etc.

2. DISPOSAL

The common methods used at the moment for the safe disposal of pharmaceutical waste are by; Ultra-high Temperature incineration and dilution then flushing in protected soak pit.

However, for specialized items such as chemicals laboratory wastes, solvents, radioactive waste etc, advice should be sought from relevant authority for this category of wastes.

WHEN TO USE THE GUIDELINES

A decision should be made by the any institution dealing in pharmaceutical products that their products are no longer needed or cannot be used for the intended purpose and therefore unsuitable for clinical use. The Institution then in writing informs National Drug Authority of the intention to dispose of the unwanted products.

PROCEDURE FOR DESTRUCTIONS

1. Original letter requesting for destruction is presented to NDA.
- 2(a) After assessment, if the pharmaceutical waste is 100kg or less, the client is given a bank slip to go and pay for the weight specified. Each kilogram of pharmaceutical waste is destroyed by NDA at fee which will be revised from time to time depending on the method of destruction and the products to be destroyed. After payment the expired items are kept in the NDA "expired drugs store".
2. (b) If the pharmaceutical waste is more than 100kg, the client is advised to contact a service provider for the destruction. In such an instance NDA shall provide an Inspector of Drugs who will supervise the safe disposal of the expired pharmaceutical wastes.

NDA charges a fee of Shs. 50,000/= per hour for the supervision of safe disposal of the pharmaceutical wastes.(Payable to NDA).

For 2(a) after payment to NDA for destruction and upon presentation of receipts the inspector of Drugs enters the particulars of the client, the expired items and the weight in the record book kept for that purpose and the drugs are kept in "Expired Drug Store" at the NDA awaiting destruction.

3. If the pharmaceutical wastes are generated by NDA during the activities of carrying out its mandate, the respective Department/Unit notifies the inspectorate department taking into account the name of items quantity and weight. This information is also entered in the record book by the Inspector of Drugs and the expired items are then stored in "expired Drug Sore"

N.B All inspectors or any NDA staff that impound any substandard pharmaceutical products should make sure that the owner of the substandard products is informed of the next intention of destruction. The owner of the substandard products is supposed to pay for the destruction of these items.

SUPERVISION OF DESTRUCTION

When the "Expired Drug Store is full (Ref. 2a), the inspector of Drugs through the Head of Inspectorate requests procurement unit for a service provider for Destruction of Pharmaceutical waste. The inspector should provide the following information and documents together with the request. This is in the case of 2(a) and 3 above.

1. Letter form NDA recommending destruction
2. List of expired items recommended for destruction
3. Weight in kilogrammes of expired items
4. Evidence (receipt) of payments for destruction, in case of 2 (a) above
5. Name of owner/client of the expired pharmaceuticals

When the service provider has been identified by procurement unit, the inspector of Drugs requests for facilitation to proceed to supervise the disposal of the expired items

After destruction, the service provider formally request NDA for payment of the destroyed drugs. The inspector must endorse on this request conforming the quantity of the items destroyed and the time taken to destroy them.

In all case, after safe disposal of the expired pharmaceutical items, the inspector provides a report which includes evidence of destruction of the pharmaceutical wastes.

After safe disposal of the pharmaceutical wastes, in case of 2 (b) above, the inspector drugs who participated in the destruction, advices finance department to bill the owner/client of the disposed expired drugs for the supervision fee and then the owner/client is issued with the Destruction Certificate after payment of the supervision fee.

It is mandatory that the following people witness the destruction process and subsequently endorse on the destruction certificate: - pharmacist in charge/technical person representing the client, the proprietor and the URA chemist