Kilimanjaro Christian Medical Centre
KCMC-Duke University Kilimanjaro AIDS Program
DIADS Clinical Research Site
Pharmacy Procedures

Procedure for Disposal of Unfit Study Products

Introduction

Study products that have been returned by patients, will be placed in quarantine. Study products that have expired, have been recalled by the sponsor or are otherwise unfit for dispensing will be removed from active stock and placed in quarantine. All quarantined study products will be segregated by study and stored in a secure area that is accessible only to Clinical Research Site (CRS) pharmacy personnel. Periodically, depending on the nature of the product, the amount accumulated and the status of the study, the pharmacist will arrange for the destruction of the product as outlined below.

A. Study products that have been returned by patients
    1. Count study products as they are returned by patients and record them in the proper columns of the Study Accountability Record.
    2. Place the returned products in the quarantine storage area segregated by study.
    3. Follow the procedure below for destruction of unfit products
    4. After the products have been destroyed, record the date of destruction on the proper line of the Study Accountability Record.

B. Study products that have been removed from active stock
    1. Remove study products that have expired or will expire before they can be taken by patients, that have been recalled by the study sponsor or that are otherwise unfit for dispensing from active stock and place them in the quarantine storage area segregated by study.
    2. Record the removal of the products from active stock on the Study Accountability Record. Each entry will include the following information:
        a. Date removed (in the date filled or received column).
        b. A statement such as “For destruction” or “To quarantine” (written across the SID, PID and Date Dispensed columns).
        c. The quantity being removed.
        d. The adjusted balance of study product.
        e. The pharmacists initials.
        f. The reason for the removal may be written in the comment column (e.g. “expired” or “recalled”).
    3. Follow the procedure below for the destruction of unfit products.
    4. After the products have been destroyed, record the date of destruction on the proper line of the Study Accountability Record.

C. Procedure for disposal of unfit pharmaceutics
    1. The pharmacist will request permission for disposal of the product in writing from the Tanzania Food and Drugs Authority (TFDA).

2. The request will be accompanied by a list of products to be destroyed. The list will include trade name, generic name, strength, dosage form, package size, quantity, manufacturer, batch number and market value of each product.
3. Once the request has been received by TFDA, the Authority will send inspectors to the site to inspect the products. The inspector will verify and authenticate the list of products and determine the method of destruction to be employed.
4. The inspector will direct the pharmacist to arrange with the responsible institution or organization for destructing of the unfit products. Whenever possible, the pharmacist will arrange to have the unfit products destroyed by incineration onsite at KCMC
5. The destruction exercise will be supervised by a Health Officer, an Environmental Officer, a Policeman and a Drug Inspector.
6. Upon completion of the destruction, an unfit drug disposal form must be filled in and signed by the supervisors. After TDFA has received the form, it will prepare a certificate of destruction for the pharmacist.
7. Copies of the request to the TFDA, the list of medications that were destroyed, the signed unfit drug disposal form and the certificate of destruction of unfit pharmaceutical products from TFDA will be filed in the appropriate study notebook.
8. The pharmacist is responsible for seeing that all TFDA Guidelines for Safe Disposal of Unfit Pharmaceutical Products are followed.

D. References

1. The Republic of Tanzania Ministry of Health, Tanzania Food and Drugs Authority, Guidelines for Safe Disposal of Unfit Pharmaceutical Products (http://www.tfda.or.tz/downloads/guidelines_disposal.htm)
2. Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks, dated September 2002.
3. Kilimanjaro Christian Medical Center, KCMC-Duke University Kilimanjaro AIDS Program, Study Accountability Record.