

## Pharmaceutical Waste Disposal Brief

Pharmaceutical waste caused by the expiry of medicines is a waste of money and therefore a threat to access to medicines in constrained economies. It is also a factor leading to inefficient use of storage space in health facilities, limiting available space for inventory of usable pharmaceutical supplies. When these expiry medicines are not managed properly, they also pose potential environmental problems.

Access to medicines has increased significantly over the last decade through donor funded vertical programs (e.g. antiretroviral therapy (ART), Malaria and TB). The global pharmaceutical industry is growing and introduction of more efficacious drugs and population growth continues pose challenges to demand planning, especially in countries with weak logistics management information systems coupled with staff shortage constrains. As a result, there are increasing volumes and variety of pharmaceutical commodities that expire at health facilities. In Tanzania, the introduction of new drugs (eg. from SP to ACT for malaria treatment), changes in treatment regimens as observed in ART, global new drug developments that affect national policy decisions and challenges in implementing good storage procedures (failure to follow First-Expiry-First-Out (FEFO) inventory control) are some of the factors that have contributed to expiry of medicines in health facilities. The WHO Pharmaceutical Country Profile of 2008 estimates the level of expiries in the public sector to be at 13%.

Tanzania MOHSW has instituted disposal procedures for medicines both in the public and private sector. The Tanzania Food and Drug Authority (TFDA) published guidelines (April 2009) that are to be used with Ministry of Finance procedures for disposal of public goods for public health facilities. Justification for the reason for expiries is also needed before the actual destruction process takes place. SCMS, which globally procures over \$100M worth of ARV drugs per annum, has also developed SOPs and work instructions for its staff to follow when involved in a disposal of US Government-funded pharmaceuticals.

### The Current Context

The process of disposing of expired/unusable pharmaceuticals is seen by health facility managers and district authorities to be a stumbling block in efforts to dejunk facilities and dispose of the pharmaceutical waste. In May 2010, SCMS advisors incorporated in routine facility visits a simple fact finding study on pharmaceutical waste disposal in Mtwara region. In Mtwara rural district, it was found that the DMO and district pharmacist collect unusable pharmaceuticals from the health center and the dispensaries, and store them in an old dispensary building at Mikindani dispensary. The storage of expired pharmaceuticals did not follow proper guidelines and were mixed

with other solid wastes, posing a danger to the HCW in that facility as shown in the pictures below.



The situation in Mtwara urban was more or less the same as in Mtwara rural district. In addition to huge piles of expired stock, the facilities had incinerators which were not functional; as a result, sharps and other medical wastes ended up being thrown in pit latrines.

The process for disposal of pharmaceuticals involves the Ministry of Health and Social Welfare, The Ministry of Finance, Ministry of Environment and the Ministry of Defense. This high level of coordination makes it difficult for district officials to move the disposal process forward. Frequently, by the time approval for destruction is obtained, the amount and value of expired medicines to be disposed is more than that original request sent for approval. The process of destruction is as outlined below:

- 1 Facility prepares an inventory list of the unusable medical items and in case of primary health facilities, send the list to the District officials (DMO and DED)
- 2 Districts sends the list to the Ministry of Finance (locally) and obtain an approval from a responsible Government stock verifiers declaring the products to be written off from the government books and be subjected to disposal according to the laws. The government evaluator costs the products and informs the District. The district then waits for a letter from MOF headquarters to authorize disposal.
- 3 Upon receipt of approval to dispose, the district writes to TFDA using a form available at the TFDA zonal offices, and to Regional and DMO. This request will be accompanied with the list of the products to be disposed
4. TFDA inspects the products to be destroyed and recommends mode of disposal depending on the types of pharmaceuticals. The inspection will also include sorting of the products so as to ease disposal.
- 5 Local authorities (district evaluators, Municipal/district medical officer/ pharmacist) determine disposal site, costs and the date for destruction. Mode of destruction is proposed by TFDA.
- 6 The consignment to be disposed of is transported in the presence of the District Environmental officer, the police, the Health officer and Drug inspector.
- 7 District fill in a TFDA drug disposal form and submit to TFDA for issuance of a Certificate of Destruction of unfit Medicines

In their monthly reports, the SCMA's have also cited the fact that accumulation of unusable medicines provides significant challenges in storage of usable stock both at the MSD zones and health facilities, as they occupy limited available space which could otherwise be used. This also leads to a vicious circle as limited storage spaces makes it difficult to practice good inventory management especially FEFO. The findings in Mtwara and from SCMA reports in other MSD zones further confirmed the need to explore a large scale disposal of pharmaceuticals to alleviate the challenges faced by health facilities.

### **Proposed Approach**

As a means of improving partnership and collaboration with local institutions, SCMS proposes subcontracting an academic institution to carry out a study of the extent of the expire pharmaceutical problem, and to propose mechanisms for addressing it. The institution is expected to carry out an assessment with the following specific objectives

1. Assess the volume and categories of expired pharmaceuticals in selected sites
2. Identify documentation procedures that are in place to document expiry medicines and if are followed
3. Identify areas of improvement to address future problems
4. Identify resources that can be of immediate use for pharmaceutical waste disposal
5. Propose approach(es) for facilitating continuous disposal of pharmaceutical waste disposal in health facilities
6. Provide a estimated cost of disposing pharmaceuticals in sites visited

### **Next Steps**

- Present the activity to PSU as custodian of pharmaceuticals in MOSHW.
- Engage stakeholders in defining processes for selection of a suitable subcontractor
- Identify a subcontractor and begin the work.