

## Chapter VIII

# Drug Distribution

### OVERVIEW

An efficient and secure process for storage, distribution and appropriate utilisation of antiretroviral medications (ARVs) will be put in place in the public health system to ensure a reliable supply of medicines at all levels of distribution to avoid “stock-outs” and to prevent shrinkage and re-exportation.

To meet these two aims, the drug distribution process will include:

- Inventory management, patient prescription information and financial management systems at the national, provincial, and local levels.
- Secure storage facilities at the central, provincial, and local levels.
- Efficient and secure transport between central warehouse facilities, provincial pharmaceutical depots and public health service points.
- Training of pharmacy personnel to implement inventory management practices.
- Improved packaging to support inventory control (and to improve patient adherence).

### BACKGROUND AND RATIONALE

Each province operates its own drug depot that provides drug storage and distribution services to the public health centres in the province. There are a total of 11 provincial drug depots, including one per province, except Western Cape and Eastern Cape, which each have two. Some have strong security mechanisms and inventory-tracking information management systems in place, while others do not. Those that do not have these systems experience higher rates of theft and stock-outs.

It is estimated that in the public health sector, a significant amount of pharmaceutical products procured is lost during the process of distribution and storage. While some of this high shrinkage risk can be attributed to the product being damaged or stocked inappropriately in the drug depots or the service point pharmacies, or during the process of

delivery, the majority is attributed to theft of product. Because of the very high market value of ARVs in Europe and the United States, and because of the lack of availability of the medicines in other African nations with a high prevalence of HIV and AIDS, large-scale theft for re-exportation presents a serious risk.

## **APPROACH**

### **Provincial Level Depots**

#### ***Drug storage***

This Programme will need to ensure that existing Standard Operating Procedures at the provincial level depots are followed. ARV medicines will be managed administratively as “Schedule 5” medicines, with some additional requirements:

- An up-to-date register with a detailed listing of all products received and distributed, as well as every prescription dispensed.
- Inventory storage in a secure location, with access restricted to the person designated as responsible for the Schedule 5 stock (e.g. pharmacist, manager, specified ARV handler). The definition of a secure location is, at minimum, a padlocked room that is caged, (caged ceiling, four walls) and has a concrete floor and for pharmacies is either a caged room or a locked box.
- Order processing at depots may only be handled by the depot pharmacist, manager or specified ARV handler.
- Whether the delivery service is a government-owned system or an out-sourced courier service, the delivery service will be required to sign the shipment in and out directly in the presence of the depot pharmacist, manager or specified ARV handler. Contracts will have to be put in place between the provincial depots and their delivery services to ensure proper service, including the introduction of severe penalties in the event that an order is mishandled by the delivery service.
- Rooms where ARVs are stored will need to have air conditioning. Some ARVs, such as paediatric formulations in syrup form, will need refrigeration.

In any location where stock is stored and distributed, audits will be required every three months.

#### **Inventory management**

To ensure proper supply of ARVs to the public health service points, provincial depots will be required to process and ship an order within two business days (48 hours) of receipt. In addition, for exceptional cases where there is a local emergency, mechanisms

will be put in place that should allow orders to be processed and shipped within four hours.

Given the volume of medicines that are likely to be ordered, the number of service points, and the need for rapid turn-around, it will be necessary to place and track orders electronically within three to five years. IT systems in each provincial depot will need to be upgraded over the initial years of the programme to include high-speed Internet connectivity, and symbology-based technologies for electronic parcel tracking. Symbology-based technologies that identify the drug, the source, the destination and the patient through a patient identification number will enable the department to meet the drug handling requirements without all the manual record keeping. There still will be paper based tracking systems in facilities that do not have computer systems or reliable access to electricity.

Within five years, it is expected that this upgrading will be completed and each provincial warehouse should have one IT person on staff to maintain the ordering and processing system. An additional investment in an advanced inventory tracking system at the central procurement, provincial depot and local health facility levels should also occur to improve visibility into the drug supply at the national, provincial and local levels, and prevent stock-outs. The system should contain the following functionality:

- When stock runs low at the service points, the system will notify the provincial depot and/or the manufacturer that more stock needs to be sent.
- When the stock runs low at the provincial depot level, the system will trigger a notification to the manufacturer that more stock needs to be sent.
- In the event that stock runs low at a provincial depot and the main manufacturer is not able to supply the order, even with the contingency supply requirements, the system will: 1) check the stocks of other provincial depots to see if they are overstocked, and trigger re-route of some of that stock to the provinces that are under stocked; 2) send an order to a secondary set of manufacturers asking for an expedited supply of the medicines.

These investments in information technology will not only improve the system to manage ARVs, but should improve inventory tracking for the entire drug distribution network.

### **Pharmacies at the Public Health Service Point Level**

There are pharmacies in all of the district hospitals and most of the community health centres. In order to accommodate the ARV Programme, investments in infrastructure and human resources will be required for up to 90 percent of these sites.

#### ***Site Accreditation***

Every health facility pharmacy that wishes to dispense ARVs will need to be accredited. Minimum standards will include, but not be limited to, the following:

- Implementation of the Standard Operating Procedures for receiving, storing and dispensing Schedule 5 medicines, including the security standards described for provincial depots.
- A minimum level of buffer stock (at programme initiation, this will be four weeks' supply; by the end of year 5, it decreases to two weeks).
- A registered pharmacist on-site.

#### ***Physical Plant Upgrades***

Most public health pharmacies will have to upgrade their facilities to deal with the demands of storing and dispensing large amounts of ARVs. Site upgrades will include an expansion of storage facilities for Schedule 5 medicines and investments in the IT infrastructure to allow for online order placement and prescription information collection and management. In addition, pharmacies will need adequate rooms for patient counselling. This should strengthen pharmaceutical care throughout all services rendered.

#### ***Prescription Tracking***

A significant portion of the population moves between their homes and a separate place of work. To ensure uninterrupted access to needed medications, it will be important for individuals to be able to get prescriptions filled as they move throughout the country. Therefore, a system needs to be in place to track prescriptions throughout the country. A software module will have to be added to the inventory management system discussed in the provincial level depot section to track patient movement throughout the system (see Chapter XI, *Patient Information Systems*). This will improve tracking and follow up for all patients on chronic medication, including TB patients.

## **SPECIAL CONSIDERATIONS**

### **Contingency Stock Plans**

In order to minimize potential disruptions to ARV programme implementation, a contingency stock plan has been considered. Drug manufacturers will be required to keep a two month supply of stock on hand in their local warehouses. This requirement will help to minimize the chance of stock-outs in the country while at the same time lessening the storage demands of the provincial depots and public health pharmaceutical facilities.

### **Packaging to Optimise Adherence**

The provincial depots have a role to play in the packaging of ARVs to improve overall drug adherence. For example, using a system that is already in place in a few of the provincial depots, packaging all the separate ARVs from a single regimen into one box or bag can greatly improve the dispensing and administering of the drug. As the IT systems improve, printing the name of the prescription recipient on each package at the warehouse or depot before it arrives at the local pharmacy will greatly improve the security and accurate dispensing of the medicines at the pharmacies. This also allows for the introduction of direct-shipping options to prescription recipients. As the number of individuals on ARVs increases over time, consideration might be given to the development of capacity to provide the type of individualized, large-volume packaging that is required through contracts with local suppliers. This can be extended to other high value items and specialised treatment regimens.

## **ADMINISTRATIVE STRUCTURE**

In order to ensure the proper implementation of the drug distribution component of the ARV programme implementation, the Pharmaceutical Policy and Planning Cluster will manage the following structures:

- The Committee for Medical Provisioning (COMED) will determine the standard operating procedures as they relate to inventory management, security, and distribution of all medicines including ARVs to all public health pharmacies.
- The Heads of Pharmaceutical Services Forum will assess training programmes and materials, and ensure proper budgets are in place to deliver on the drug distribution plan.

- The Pharmaceutical Policy and Planning Cluster will oversee the pharmacy accreditation process, developing a strategy to ensure that accreditation can happen in a timely manner. Other activities will include development of standards for tracking and tracing of medicines

## **PROGRAMME ASSESSMENT**

The Pharmaceutical Policy and Planning Cluster will assess the programme on an ongoing basis, to ensure that set goals are met. Specifically, at depot level, the goals are to:

- Keep shrinkage of ARVs below 0.5%.
- Process orders within 48 hours.
- Maintain a minimum of 6-week stock at the provincial depot level.

At the pharmacy level, the goal is zero stock-outs and shrinkage below 0.5%. Manufacturers will be measured based on meeting expected lead times, the quality and completeness of orders, and the maintenance of a continual 6-week stock in local warehouses.

At facility level, the ultimate goal is to ensure that records of patients' medication profiles are kept to facilitate counselling on drug use, follow-up of patients on chronic medication that default, reporting of adverse events and adverse reactions and to link all pharmacy activities to a patient information system.