Medicines are subject to various legislative controls which affect how the medicine may be handled and the people given the responsibility of handling the medicine. Pharmacist’s assistants, like pharmacists, are governed by the Pharmacy Act whereas most of the details with regard to how to handle medicines are contained in the Medicines and Related Substances Act. This legislation sets out the following:

- How medicines are scheduled
- How the different schedules are controlled
- What records need to be kept
- How medicines should be stored
- The expiry of medicines
- How medicines should be destroyed
- Inspection procedures/requirements

The need for legislation with respect to the use of medicines is obvious, but how is it implemented? South Africa is unique in Africa in that medicines control is based on a closed medicine register. This means that any medicine to be sold or dispensed in South Africa must be approved by the Medicines Control Council. Approval is based on the following:

- Quality  The medicine must meet the prescribed quality standards
- Safety  The medicine must be safe for the indications specified
- Efficacy  The medicine must be effective for the indication it claims to treat.

Once the medicine has been registered it is allocated to a category or ‘schedule’ indicated by an S. There are 9 medicine schedules (S0  S8) of which only seven are available to the public provided that certain conditions of supply are met. The higher the scheduling status of a medicine, the greater the control over that medicine needs to be.

What does the schedule of a medicine imply?
Many people believe that a medicine schedule is an indication of its strength, potency or efficacy. Many patients will refer to Schedule 5 sleeping tablets or pain medication as ‘really strong’ as opposed to Schedule 2 medicines that are often seen as ‘ineffective’ because one does not require a prescription. This is a misconception and it is important to understand that a schedule is assigned to medicine on the basis of four very important factors, namely:

- The product’s safety profile i.e. the product may be dangerous if not used correctly
- The product’s potential for abuse, i.e. the degree to which the patient may become dependent on the product
- The importance of a correct differential diagnosis
- The need for management of the condition by a healthcare professional

In other words a Schedule 0 product which can be sold by anyone in an open shop is generally safe and does not carry a big risk of abuse when sold in the standard pack size and when used according to the directions given in the package insert. However a Schedule 6 product implies possible danger and a high potential for abuse, for example morphine.

One very easy way to illustrate this point is to consider codeine which is Schedule 2 when contained in low doses in combination products such as cough suppressants and oral analgesic preparations. Codeine is, however, also available in a 30mg single dose which is then registered as a Schedule 6 medicine. These different products all contain the same compound but have different schedules based on the amount of codeine incorporated since the dosage determines the severity of the side effects experienced and the likelihood of the patient abusing the product. Care must be taken to ensure that patients do not use excessive amounts of a codeine containing product in order to avoid
the dangers associated with the Schedule 6 product.

It is also important to note that no matter what the schedule, no medicine should be regarded as ‘completely safe’. Patients must realise that taking a medicine, whether it is prescribed or not, interferes with the body’s natural function and therefore may have some risks associated with it.

How are the different schedules controlled?
Now that we understand the basis on which a schedule is assigned to a product, it is logical that the sale of scheduled products be regulated accordingly and the control over the sale of these products must increase as the schedule increases.

Control over these products includes control over who may sell or dispense the product and to whom it may be sold or dispensed, for example whether or not the product may be sold to children under the age of 14 years. Other forms of control include control over whether the product may be issued on a verbal prescription or be issued in an emergency, whether or not it may be repeated and the record keeping requirements when dispensing the product.

What about the storage and advertising of medicines?
The Medicines and Related Substances Act also specifies how medicines should be stored and how they may be advertised.

Again there are different requirements for the storage of each schedule, namely schedule 0 and schedule 1 products may be stored anywhere in the pharmacy, whereas schedule 2 products may not be accessible to the public and should be handed out only by a person authorised to do so (e.g. pharmacist, intern and post basic pharmacist’s assistant). Schedule 3 to 5 products must be stored in the dispensary and Schedule 6 products must be locked away in a separate cupboard within the dispensary. Again it is evident that the control over the storage of these medicines increases as the schedule increases. In addition it is important to comply with the recommended temperature for storage of medicines, particularly heat sensitive products which must be kept in the fridge.

With respect to advertising, Schedule 0 and 1 products may be advertised to the public, whereas Schedule 2 to 6 medicines may only be advertised to health professionals such as medical practitioners, dentists, veterinarians and pharmacists. These advertisements usually appear in brochures or pamphlets handed directly to the health professional or publications which are not normally available to the public. However, the public may be informed of medicine names, prices, pack size and strengths, but not indications or other information may be provided. This information is usually in the form of lists and may not include advertising pictures or ‘pack shots’ of the product. It should be noted that these conditions also apply to websites advertising medicines.

How should medicines be destroyed?
The Medicines and Related Substances Act also specifies that all medicines must have an expiry date. Most medicines have a shelf life of two years, provided that they remain in their original packaging. Once a medicine has been removed from its original packaging, the shelf life automatically reduces to a maximum of 6 months due to the fact that the exposure to heat and humidity is no longer controlled. A medicine may not be sold after it has passed the expiry date and must be returned to the supplier or destroyed. Every pharmacy should have a policy of doing a monthly check for expired or ‘soon to be expired’ medicines and removing them from the shelf.

Medicines which have expired or which have lost quality cannot simply be thrown away, but must be disposed of responsibly. This includes not throwing medicines down the drain or into the toilet. All scheduled medicines must be written off by a pharmacist and recorded before being returned to the supplier for destruction. Products which are contaminated with blood or biological fluids (e.g. syringes) must be thrown into a protective container called a ‘sharps bin’ which, when full, will be destroyed by incineration. Finally the destruction of Schedule 6 medicines must be authorised by a Medicine Control Council inspector.

In conclusion, compliance with both the Pharmacy Act and the Medicines and Related Substances Act is checked using inspectors from both the South African Pharmacy Council and the Medicines Control Council. These inspectors visit pharmacies, hospitals, wholesalers and manufacturers and are generally very willing to offer advice on the proper procedures. It is, however, important that both pharmacists and pharmacist’s assistants understand their legal responsibilities and make every effort to comply with these very necessary regulations.