Understanding the medicine schedules
Part 2 – Schedules 3 to 8

Lorraine Osman

In the last issue of SAPA, we examined the impact of Schedules 0, 1 and 2 on your practice. In this issue, we look at the types of control for supply of Schedules 3 to 8 substances in a pharmacy.

Please note that the article refers to pharmacist’s assistants throughout, and does not mention Pharmacy Technicians or Pharmacy Technical Assistants. The article applies to both Post-Basic Pharmacist’s Assistants and Pharmacy Technicians, as they are currently practising within the same scope of practice.

Before examining Schedules 3 to 8, we need to remind ourselves of the factors that the Medicines Control Council (MCC) takes into account when allocating substances and medicines to a Schedule.

Factors which influence the scheduling a substance or medicine

Deciding on a schedule for a substance or medicine is a complex process. Each individual substance is critically examined for each of the considerations, and a decision is made. Some of these factors are:

- Evidence for the toxicity of the substance and the safety in use
- The indication for the substance
- The need for medical diagnosis, monitoring and medical management by a healthcare professional
- The potential for abuse
- The need for access to the substance

Schedules 7 and 8

Let’s start with the easy ones. The bottom line is they cannot be supplied in pharmacies, or any other place, and they may not be advertised to the public. Obviously, universities doing legitimate research may request permission to keep the substances. So what’s the difference and why don’t we just put all these substances into schedule 7?

Schedule 7

The substances that are listed in schedule 7 are those which are likely to be abused or produce dependency. They are also not recognized as having medical use. Who hasn’t heard of dagga, khat, heroin, LSD? And what about methamphetamine derivatives, like Molly, crystal meth and tik? We hear about them every day in the news, and the disastrous effects that they have on users and their families. These are examples of Schedule 7 substances – their possession and use is forbidden because not only do they produce undesirable effects, there is also no justifiable reason for their use. There is obviously one exception – if someone is conducting scientific research, they may apply for permission to do so.

Schedule 8

There are only three substances listed in Schedule 8 – amphetamine, dexamphetamine and nabalone. All three are also listed in Schedule 7, because their abuse and dependency profile is similar to other Schedule 7 substances. The notable difference, though, is that there is some recognised medical use. The high abuse and dependency potential make it undesirable to make them generally or widely available, but if a medical practitioner believes that one of these is the only substance that will assist a specific patient to control a specific medical condition, he or she may obtain special permission from

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the MCC to prescribe and supply it to the patient. The Director-General of Health will then make the substance available.

**Schedule 3 to 6 medicines**

Let's return to the medicines that can be supplied in a pharmacy. Schedule 3 to 6 medicines have a lot in common – they are all prescription medicines that must be prescribed by an authorised prescriber, i.e. a medical practitioner, dentist or vet, or someone authorised in terms of the Medicines and Related Substances Act, 101 of 1965. This is because they have similar characteristics.

Generally, the higher the schedule, the more control is required by the healthcare professional. In addition, it may be higher because of increasing risk of misuse and abuse.

- The symptoms and conditions cannot be handled by self-care, self-diagnosis and self-medication. The first step is that an accurate diagnosis must be made by a doctor, dentist or vet. In the case of a public sector primary health care clinic, this function is performed by the nursing sister. Laboratory tests may be necessary before the diagnosis is made, as well as physical examination or other clinical assessment.

*Example:* During Pharmacy Week last year, we spoke about inappropriate use of antibiotics. This is why most antibiotics must be obtained on prescription, although some for topical use may be sold without a prescription.

- The example above is reinforced by another guideline of the MCC – substance may be placed in a higher schedule use has contributed to communal harm, or if it may do so.

*Example:* Antibiotic resistance is a prime example of this and explains why the decision to initiate antibiotic treatment must only be made after the patient's condition has been evaluated by a medical practitioner.

- Although the pharmacist can assist in monitoring some chronic conditions, the medical practitioner must take responsibility for management of the condition, especially if the risk of complications is high.

*Example:* Uncontrolled diabetes can lead to a number of serious or even fatal problems like heart disease, and damage to nerves, kidneys, eyes and feet.

- The prescriber must also determine how long the therapy is to continue.

*Example:* In the early stages of diabetes or hypertension therapy, for example, the prescriber may want to see the patient frequently so that the effects of the medicine and the doses used can be checked. Prescriptions for a short time, such as a few weeks at a time, are not unusual at this stage of therapy. When the condition is stabilised, the doctor may give a prescription that can be filled at regular intervals.

“Generally, the higher the schedule, the more control is required by the healthcare professional.”

- Serious or severe side effects are another reason for putting a medicine into a higher Schedule.

*Example:* Chloroquine may sometimes be used at high doses for treatment of rheumatoid arthritis or systemic lupus erythematosus, but the patient needs regular eye checks because vision may be affected. Even if used in the treatment of malaria, it is contraindicated in cases such as pregnant women and patients with porphyria or liver disease.

- When a substance is useful therapeutically but has the potential for misuse, abuse or illegal use, the controls are also stricter than with those that can be bought without a prescription.

*Example:* Some ingredients used in sleeping tablets or as analgesics fall into this category.

- The difference between the dose that has a therapeutic effect and the toxic dose is very small, so frequent monitoring is needed.

*Examples:* Digoxin, warfarin, phenytoin, theophylline

- Although medicines must have undergone clinical trials before they can be registered with the MCC, these trials are conducted under strict but limited circumstances. Unexpected effects may arise when a product is used by the general population. In some cases therefore a substance will be made prescription-only so that the patient can be closely monitored. If after some years it becomes obvious that a particular substance, if taken correctly, is safer than originally thought, it is possible that it will be moved to a lower schedule, at a particular dosage and for a particular indication. This will be dealt with in part 3 of this series.

**Schedules 3 to 6**

There are both similarities and differences between various aspects of control of these schedules, so they will be compared as a group. When it comes to the reason why a substance is in one of these schedules, remember that all the factors listed above must be considered. So you will find that medicines for chronic conditions that need accurate diagnosis and ongoing management with medicines, e.g. hypertension medicines, are frequently in Schedule 3, while many medicines that need accurate diagnosis but are for short term use only, e.g. antibiotics, are in schedule 4. These are not hard and fast rules, because it depends on the evidence available. A medicine may be for a chronic condition that can be managed by the patient for 6 months,
but because of the other characteristics of the medicine, it may be placed in Schedule 4 or 5.

Many of the medicines that fall into Schedule 5 and 6 have psycho-active properties, i.e. they affect the brain in one way or another. They also have been proved to have potential for misuse or abuse. Examples are the sleeping tablets and tranquillisers. Other medicines, such as anabolic steroids, are also in Schedule 5 because they need to be controlled for legitimate use and it is known that they are misused.

“All medicines that fall into Schedule 5 and 6 have psycho-active properties”

All prescriptions must be triaged by a pharmacist, in other words the pharmacist must evaluate the prescription to see what can be delegated to the pharmacist’s assistant.

*Who can buy them?*

These medicines can only be supplied to someone with a legal prescription.

*Can a pharmacist’s assistant sell or dispense them, and who signs the prescription?*

Phase 1 – only the pharmacist may evaluate a prescription to see whether items prescribed for an individual are appropriate. The pharmacist must check legality, content and correctness of the prescription. Other aspects that must be evaluated include the dosage, safety of the medicine, interactions with other medicines used, pharmaceutical and pharmacological incompatibilities, treatment duplications and possible allergies to the medicine prescribed.

Phase 2 – a pharmacist may prepare the medicines, or may delegate this to a pharmacist’s assistant. This phase involves picking, packaging and labelling of medicine, as well as checking expiry dates and keeping appropriate dispensing records.

Phase 3 – the pharmacist must decide which patients need counselling from the pharmacist. These patients include:

- those who are taking many different medicines for different conditions – there is a greater possibility of interactions
- those whose medicine regimen is complicated, because it is critical that the patient understands how and when to take the medicines
- someone who is receiving medicine for a newly diagnosed chronic condition
- people who have a habit of not taking medicine correctly or regularly.

In straightforward cases where all that is needed when handing over the medicines is to provide instructions on how to take the medicine safely and effectively, the pharmacist may delegate the handing over to the pharmacist’s assistant.

The pharmacist must take overall responsibility and must check the assistant’s work. It is therefore logical that the pharmacist must sign the prescription. It is also logical that the assistant must sign and take responsibility for those aspects that were performed by him or her, such as preparing the medicines or handing them out.

In the case of Schedule 6 medicines, the pharmacist must perform all phases of dispensing. The exception is when a pharmacist’s assistant is working under indirect supervision in a primary healthcare clinic. Although at this stage only injectable Schedule 6 medicines are usually kept in the clinic, if the Primary Health Care Standard Treatment Guidelines are changed to include oral or transdermal preparations, the pharmacist’s assistant would be permitted to dispense it to a patient, provided that it was supplied to the clinic in a patient-ready pack.

**Record keeping**

All details of the prescription must be kept in a permanent record or prescription book.

Details to be recorded:

- the name of the medicine
- the date on which the prescription was dispensed
- the dosage form and quantity of the medicine or scheduled substance
- the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold
- the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription
- the prescription reference number

“All prescriptions must be presented for dispensing within 30 days after they were written.”

All transactions involving Schedule 6 must, however, be recorded in a register as well. The register must also be balanced four times a year to make sure that the physical stock present is the same as that recorded in the register.

All prescriptions must be kept for a period of five years after dispensing.

**Validity of prescriptions**

All prescriptions must be presented for dispensing within 30 days after they were written. This makes sense – if the
doctor decided that the patient was ill enough to need medicine, he or she usually intends the patient to take the medicine at once. You cannot take it for granted that more than a month later, the patient still needs the medicine.

**Information required on a prescription**

- The name, qualification, practice number and address of the prescriber or authorised person placing the order
- The name and address of the patient in the case of a prescription or the name and address of the person to whom the medicines are delivered in the case of a prescription issued by a veterinarian
- The date of issue of the prescription or order
- The approved name or the proprietary name of the medicine
- The dosage form
- The strength of the dosage form and the quantity of the medicine to be supplied
- In the case of a prescription, instructions for the administration of the dosage, frequency of administration and the withdrawal period in the case of veterinary medicines for food producing animals
- The age and sex of the patient and in the case of veterinary medicine, the animal species
- The number of times the prescription may be repeated. For Schedule 5 medicines, the intervals between dispensing must be indicated. Schedule 6 medicines cannot be repeated – a new prescription must be obtained every time.

**Quantities that may be dispensed**

For Schedule 2, 3 and 4 medicines, 25% more or less than prescribed may be supplied, provided that it is supplied in the quantity contained in the therapeutic pack in the original container. Obviously, this must be recorded on the prescription.

Schedule 6 medicines may not be provided for more than 30 consecutive days.

**Verbal prescriptions**

Although written prescriptions are always preferable, there are circumstances when a prescriber, who is known to the pharmacist, may give verbal instructions to the pharmacist. In this case, the prescriber has seven days to provide a prescription confirming the verbal instructions. If it is a repeat prescription, the pharmacist’s assistant may take the instruction, but new prescriptions must also be taken by pharmacist.

**Advertising to the public**

Schedule 3 to 6 medicines may not be advertised to the public, but they may be advertised for the information of medical practitioners, dentists, veterinarians, pharmacists in a publication which is available only to these professionals. Some details however may be used to inform consumers. These are the prices, names, pack sizes and strengths of medicines. It is not appropriate or permitted to sing the praises of these medicines in an advertisement in a publication for consumers!

**Coming up next**

Part 3 – medicines that appear in more than one schedule