

The Medicines and Related Substances Control Act: Essential facts about dispensing licensing, scheduling and generic substitution

LICENSING

All health care professionals wishing to continue to compound and/or dispense medication to patients have to, in terms of the 1997 and 2002 amendments to the Medicines and Related Substances Control Act of 1965, apply for a dispensing licence. The following requirements are, among others, set for this application:

- Proof of completion of an accredited dispensing course, set by the Pharmacy Council after consultation with the various statutory bodies (HPCSA, Nursing Council, etc.). For medical practitioners the course is provided by the Foundation for Professional Development (FPD) in a distance education format.
- Provision of justification for a licence, including the health profile and number of health care users in a certain area. This requirement means that it is, in theory at least, possible to have more than one dispensing facility in a certain area, provided that the health care user and population profiles justify the existence of two dispensing facilities.
- Proof that interested parties were invited in a local newspaper to make submissions on the intended licence application to the authorities.

The licence, once granted, will be valid for a period of 3 years. It is not clear from the regulations whether a licensee will have to do any refresher or update courses or whether an application will only be for an extension. Unsuccessful applicants have a right to appeal against a turned down licence application. The grounds for such an appeal will be, for the greater part, based on the field of administrative law. The rules of administrative law set a number of rules that the authority evaluating applications have to adhere to.

The provision in the Health Professionals Act of 1974 in terms of which doctors could apply to the HPCSA for a dispensing licence, will be repealed as from 2 May 2004. Dispensing practitioners will therefore have approximately 8 - 9 months to complete the course and apply for the licence to the Department of Health.

Practitioners who 'compound and dispense' by providing and preparing a medicine for a once-off administration to a patient during a consultation would not require a dispensing licence.

SCHEDULING

Practitioners should be aware of the changes brought about by section 22 and 22A of the Act, as well as new provisions on record-keeping of, for example, over the counter medication, specified Schedule 5 and Schedule 6 products. It is also important to note that the scheduling system has changed, starting at Schedule 0. Practitioners are advised to obtain copies of these changes. Where a practitioner prescribes a product for its anxiolytic, antidepressant or tranquillising properties, such a practitioner has to consult with a psychiatrist first. In the case of analgesic prescriptions exceeding 6 months, the practitioner has to consult with another practitioner. It is advised that this fact be noted, as extensively possible, in both the patient's file and on the script itself.

Generic substitution

Any dispenser, including medical practitioners currently dispensing, has to substitute a generic medicine in all but a few exceptions. The dispenser has to dispense a medication of 'therapeutic equivalence', which is defined in regulation 2 as 'pharmaceutically equivalent', i.e. both products must:

- contain the same amount of active substances in the same dosage form
- meet the same or comparable standards
- be intended to be administered by the same route
- after administration in the same molar dose, have essentially the same effects with respect to both efficacy and safety.

No substitution may take place:

- if the patient prohibits such substitution
- where the prescriber has written in his or her own handwriting next to the line item 'no substitution'
- where the generic product is more expensive
- where the product has been declared non-substitutable.

Practitioners who are interested in the dispensing course should contact the FPD at tel (012) 481-2034/2101. A number of scholarships are available to lower course costs drastically.

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