



A guide to obtaining a licence to dispense medicines

Diane Harrington,
BA Nursing
(Pret.), M.Cur
(Pret),
RN., RM.,
OHNP –
Occupational
Health Services
CC.
eden@acenet.co.za

The controversy relating to the issuing of Dispensing Licences, and the pending court cases, do not relieve the Occupational Health Nurse Practitioner (OHNP) from the responsibility to apply for the applicable licence. As there is much confusion and many rumours regarding what is required, this article provides a guide to the steps to be followed and the documents that must be submitted.

The OHNP is required to:

1. Obtain a Certificate of Competence to Dispense Medicines. If you are currently doing the course, you should request proof of registration from the applicable institution. (Although your company is not obliged to pay for the Dispensing Course, it may be prepared to do so).

2. Arrange for her/his company to pay the stipulated Application and Licence Fees. As the Department of Health (DOH) does not provide invoices, the following documents can be downloaded from the DOH's website (see below) so that you are able to give your company proof of the Department's requirements:

Relevant legislation:

- The Medicines and Related Substances Control Act (No. 101 of 1965, as amended), Section 22C, D and E
- General Regulations of the Act (Government Gazette No. 510, dated 10 April 2003), Section 18.

Application Form:

- Application for a dispensing licence, and
- A Section 38A authorisation to diagnose and prescribe.

Fees:

- Government Notice re: Application and Licence fees.

Guidelines:

- Guidelines for completing an Application Form for a dispensing licence.

Note: The DOH website is available at www.doh.gov.za/docs/forms, Pharmaceutical Management Information System – Licensing Issues.

3. Arrange for her/his company to place the required advertisement in the local newspaper. This advertisement should:

- State the name of the OHNP and that she/he intends applying for a Licence to Dispense Medicines.
- State the name and physical address of the Company

where the OHNP intends to dispense medicines, and

- Specifically state that the advertisement has been placed in order to comply with the Medicines and Related Substances Control Act (No 101 of 1965), as amended.

4. Complete and submit an Application Form, as per DOH Guidelines.

Note: The following documents should be attached to the Application Form:

- Bank guaranteed cheque for R1000.00.
- S.A. Nursing Council receipt for payment of fees for 2004.
- Copy of the local newspaper advertisement, reflecting the name of the newspaper and the date of publication.
- Certificate of Competence to Dispense Medicines, or proof of registration for the course.
- Authorisation to Diagnose and Prescribe under Section 38A of the Nursing Act (No. 50 of 1978), signed by your Company doctor this year.
- Copy of the current permit, if the clinic has one.

It is advisable to deliver the application by hand (your messenger must get a signature from the recipient), or send it by registered post. The DOH should send you a receipt in due course. You may be advised that your clinic has to be inspected.

If an inspection of your clinic is required, it will be done by a member of the Pharmacy Council. The purpose of such an inspection is to ensure that the clinic conforms to 'Good Pharmacy Practice', as laid down in the Guidelines under the same name. The Inspector will want to verify the various items listed on the Application Form, especially Section E, and in my own case the Inspector also checked:

- That I had obtained the Certificate of Competency to Dispense Medicines.
- The type of containers/tablet packets used.
- That storage of medicines conformed to the guidelines.
- Ordering and record keeping were as prescribed.

The Inspector also recommended that a daily record be kept of the temperatures within both the clinic room and the clinic fridge. The use of a room thermometer, starting at minus 10°C or less, is acceptable and costs about a quarter of the price of a fridge thermometer.

I hope that the above comments and suggestions will be of assistance.

Good luck with your application.