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Dear Mr Drummond


**INFORMATION WITH REGARD TO A CONCESSION IN TERMS OF SECTION 22A(12)
OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF
1965) AND SECTION 38A OF THE NURSING ACT, 1978 (ACT 50 OF 1978)**

Attached, please find information on recent decisions taken in respect of the management of concessions in terms of section 22A(12) of the above Act.

The reasons for not currently issuing section 22A(12) permits for Occupational Health Clinics or nurses in private practice, are explained, as well as the use of section 22A(12) permits in combination with Section 38A of the Nursing Act.

It is trusted that this information will be of use to you.

Kind regards


DIRECTOR-GENERAL
DATE: 2007-02-04



THE APPLICATION OF A CONCESSION IN TERMS OF SECTION 22A(12) OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965) AND SECTION 38A OF THE NURSING ACT, 1978 (ACT 50 OF 1978) TO LEGALISE NURSES WORKING IN OCCUPATIONAL HEALTH CLINICS.

Section 22A(12) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) is a concession granting an organisation or a person rendering a health service the right to be authorised by the Director-General: Health to acquire, possess, use or supply any specified Schedule 1 to 4 substance. This allows a permit holder to acquire (access) and supply schedule 1 to 4 medicines.

Legal opinion obtained on the granting of permits indicated that a concession in terms of section 22A(12) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) does not authorise nurses or other health practitioners to diagnose, prescribe and dispense scheduled medicines. A section 22A(12) permit allows a permit holder to only acquire (access), possess, use and supply medicines. In addition any schedule 3 and 4 medicines may not be used or supplied without a valid prescription.

Currently, neither the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) nor the Nursing Act, 1978 (Act 50 of 1978) makes provision for nurses in the private sector to diagnose and prescribe.

To enable Industrial Organisations to continue rendering these essential primary health care services, an interim solution with regard to Occupational Health Clinics needed to be in place.

Section 38A of the Nursing Act, 1978(Act 50 of 1978), does however make provision for the Director-General: Health to **designate** Industrial Organisations as organisations rendering health services, after consultation with the Pharmacy Council of South Africa. This then authorises the medical practitioners in charge of the clinics to issue section 38A permits to nurses working in Industrial Clinics.

These nurses will then be allowed to:

- (a) Physically examine any person;
- (b) diagnose any physical defect, illness or deficiency in any person;
- (c) keep prescribed medicines, supply, administer or prescribe on the prescribed conditions and
- (d) promote family planning.

In terms of conditions set by the Department of Health for the issuing of section 22A(12) permits, the requirements are that a Medical Practitioner as well as a registered nurse must be in the service of these Organisations.

Approval has therefore been obtained from the Director-General: Health, after consultation with the South African Pharmacy Council and the South African Nursing Council, for the designation of Industrial Organisations performing a health service, thus authorising medical practitioners in charge of the clinics to issue Section 38A permits to nurses working in Industrial Clinics.

In meetings held with the South African Pharmacy Council, the Nursing Council of South Africa, the South African Society of Occupational Medicine and the South African Society of Occupational Health Nurses the following decisions were taken:

- No new applications for section 22A(12) permits are currently being considered.
2. Permit holders who have responded to a request, sent out in July 2000, to supply information regarding the current status of their service provision, will retain their permits. These permits will be valid until the end of June 2002.
 3. Nurses in clinics will be authorised to diagnose, prescribe and dispense medicines by means of the issuing of permits by the medical practitioner in charge of the clinic in terms of Section 38A of the Nursing Act, 1978 (Act 50 of 1978). A section 22A(12) concession in terms of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965) will allow them to acquire (access), possess, use and supply schedule 1 to 4 medicines.

The list of permit holders is available on the Internet with the following URL:

<http://pharmis.pwv.gov.za>

It can be accessed at "Permit Information" on the Website. As it is a large file it has to be downloaded and then unzipped

4. Nurses working in private practices cannot be authorised in terms of section 38A.

WAY FORWARD:

1. The Medicines and Related Substances Control Amendment Act, 1997 (Act 90 of 1997) was signed by the President in 1997. This Act has not been proclaimed as a result of the interdict obtained by the Pharmaceutical Manufacturers Association in 1997. The interdict has now been resolved and the finalisation of the Regulations to this Act is awaited.
2. Once proclaimed, the Act will acknowledge a nurse as a prescriber. The nurse will then be authorised by the Nursing Council to diagnose and prescribe. If she wants to dispense she will have to apply to the Department of Health for a licence to dispense after she has successfully completed a supplementary course prescribed by the Pharmacy Act.