Regulations relating to the Ownership and Licencing of Pharmacies

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The Minister of Health has, in consultation with the South African Pharmacy Council, in terms of sections 22 and 22A of the Pharmacy Act, 1974 (Act No. 53 of 1974), made the regulations in the Schedule.

Conditions for the ownership of pharmacies

7. (1) A person who may own a pharmacy in terms of section 22A of the Act and who applies for a licence in terms of section 22 of the Act shall provide the Director-General with -

a. proof that such person is able to comply with standards of Good Pharmacy Practice as determined by the council, and where applicable, Good Manufacturing Practice or Good Distribution Practice as determined by the Medicines Control Council, a body established in terms of section 2 of the Medicines Act; and

b. an undertaking that such person shall comply with standards referred to in paragraph (a).

(2) The person referred to in subregulation (1) must satisfy the criteria for the determination of a need for the pharmaceutical service in respect of an area for which the application is made, which includes but is not limited to-

a. the location of the premises applied for;

b. the benefit to members of the specific community which the pharmacy intends serving;

c. the nature and extent of the pharmaceutical service to be provided;

d. a statutory requirement for the location of a pharmacy within a private or public health facility;

e. the approximate number of the population to whom a pharmaceutical service will be provided;
f. the relationship between the proposed pharmaceutical service and existing services and facilities;

g. the extent of the provision of services to persons outside the service area and the extent and nature of the availability of pharmaceutical services in the nearby areas;

h. any special care needs of the community to be served;

i. an inspection report by the council of the premises.

**Licensing process**

The process starts where the Proposed Licence Holder (PLH) has to be registered with the Registrar of Companies within the republic. Once the PLH is a registered company it will then have to follow the following two principle acts namely: Pharmacy Act (Act 53 of 1947) and the Medicines and related substance act (Act 101 of 1965) in order to handle pharmaceuticals. By ‘handling’ we refer to: manufacture, Import, Export, Warehouse, Distribute and testing of medicines.

A PLH that handles pharmaceuticals is deemed a pharmacy. Thus the facility would have to be conducted under the direct personal supervision of a responsible pharmacist, this pharmacist has to be registered with the South African Pharmacy Council (SAPC), firstly as a pharmacist and then also as a Responsible Pharmacist under the PHL name. This process is governed by: Pharmacy Act 53 of 1947, Section 14: Registration of persons, recording of licensed premises and maintenance of registers. SAPC conduct an inspection of the facility before awarding certificates to the PLH. The PLH will have proof that the facility complies with standards of Good Pharmacy Practice as determined by the SAPC.

The next step is applying to the Department of Health. Two applications need to be completed by the PLH (usually completed by the Responsible Pharmacist) to the Department of Health (DoH); these applications can be done simultaneously. The one application is to licence the premises with the DoH as a site that will be handling pharmaceuticals (Licence wherein the Pharmacy business can be conducted), and the second application is to the Medicine Control Council (MCC) for a licence to conduct one or more of the following: compound or dispense, manufacture, Import, Export, Warehouse, Distribute, wholesale and testing of medicines. (An application form for the purpose of obtaining a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C read together with Regulation 19 of the Act.). Please note the MCC will conduct an inspection of the facility before awarding
a licence. The PLH will have to proof to the MCC that the facility is conducting business in accordance with Good Manufacturing Practice or Good Distribution Practice standards.

Both licences need to be submitted to the SAPC once obtained and this will complete the initial licensing process.

The MCC licence is valid only for 5 years and renewal is necessary after 5 years. Application forms are completed for renewal and an inspection can be conducted at the discretion of the MCC.

A Licence application fee is payable to the MCC by the PLH upon application and retention fees are payable annually for both the pharmacy registration (paid to the SAPC) and the MCC licence (paid to MCC).

Flow diagram summarising the licensing process that the Proposed Licence Holder would have to undertake.