MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

GUIDELINES FOR LICENCE TO ACT AS A WHOLESALER or DISTRIBUTOR

This guideline is intended to provide recommendations to applicants wishing to submit an application for a licence to act as a wholesaler of or distribute medicine or medical devices. It is not intended as an exclusive approach leaflet and should not be taken as a complete or authoritative statement of the law. Council reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine or medical device in keeping with the knowledge current at the time of evaluation. The MCC is committed to ensure that all medicine or medical devices will be of the required quality, safety and efficacy and that the wholesaler / distributor complies with acceptable quality assurance principles and good wholesale / distributor practices as determined by Council. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

The guidance in this Guidelines and application forms are available from the office of the Registrar of Medicines and the website.

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REGISTRAR OF MEDICINES

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1 INTRODUCTION

The Medicines Control Council (MCC) regulates medicines for human and animal use, on behalf of the Department of Health and in accordance with the provisions of the **Medicines and Related Substances Act, 1965 (Act 101 of 1965)** and the relevant Regulations made thereunder. (Hereafter referred to as the Act or the Medicines Act.)

Amongst other things, it is unlawful for medicines or medical devices to be marketed, manufactured, distributed and sold or supplied in the Republic except in accordance with the appropriate authorisation, registration certificates, licences, clinical trial approvals or exemptions obtained from the Medicines Control Council.

The licensing system includes the Council, the Registrar of Medicines and the Directorate: Inspectorate and Law Enforcement, whose duties comprise the issue of licences to those engaged in the sale or supply of medicines and medical devices by way of wholesale dealing. Further, the GMP Inspectorate and the Council are responsible for ensuring that licence holders comply with the provisions of their licences.

The wholesale or distribution of veterinary medicine or medical devices for animal use, registered with the Medicines Control Council in terms of the provisions of the Medicines and Related Substance Act, 1965 (Act 101 of 1965), is subject to the same legislation and the requirements are similar.

The purpose of this Guidance Note is to provide guidance on the law covering the wholesale distribution of medicines and medical devices and wholesale dealing of medicines and medical devices for human and animal use and controlled in terms of the provisions of the Medicines Act.

2 WHOLESALE DEALING OR DISTRIBUTION

2.1 All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public, are wholesale distribution.

2.2 Wholesaling of unregistered medicinal products e.g. investigational medicinal products, or medicine solely for export purposes are also controlled in accordance with the relevant provisions of the Act and the regulations.

2.3 Wholesale dealing is the sale of medicinal products in the course of a business, to a person who buys it for sale or supply, or for administration to a human being or animal. Therefore, wholesale dealing entails any sale or supply except to the end-user (patient). Such sale by the manufacturer is not included.

2.4 Section 22C of the Medicines Act read together with Regulation 1 provides that:

"wholesaler" means a dealer or trader who acquires any medicine or medical device from a manufacturer and sells or distributes it to the retail sector and includes a wholesale pharmacy.

2.5 Section 22H of the Medicines Act prohibits any wholesaler from buying any medicine from any other source except from the original manufacturer or from the primary importer of the finished product, except when specifically exempted by the Director-General from such provisions.

3 PERSONS REQUIRING A WHOLESALE DEALER'S LICENCE

3.1 Persons who in the course of a business are engaged in:

(a) wholesale distribution of medicinal products

(b) wholesale dealing of medicinal products for human and animal use

requires a wholesale dealer's (WL) licence, unless exempt.

4 HOW TO OBTAIN A LICENCE

4.1 Standard application forms for wholesale dealer's licences (WL) to act as a wholesaler of or distributor of medicines or medical devices are available from the Registrar of Medicines or on the Medicines Control Council's website at www.MCCZA.COM.

4.2 An application for WL should be accompanied by the prescribed application fee and in the case of a new Wholesaler an inspection fee. The applicant should provide acceptable documentation proof obtained from:

4.2.1 the SA Pharmacy Council, of:
- the particulars of the owner of the business, which includes the Certificate of recording of a Pharmacy Owner
- the registration of the responsible pharmacist
- Certificate of recording of a Pharmacy.

4.2.2 the Director-General of Health:
- a licence for the premises wherein or from which such business shall be carried on.

NOTE: All wholesalers in operation prior to 2 May 2003 are deemed to have a premises licence.

4.3 The application for WL should include the qualification of staff to store, distribute and sell medicines, scheduled substances or medical devices and should be able to comply with good wholesale / distribution practices as determined by Council.

4.4 The application should include:
- A copy of the local area plan of the location of the business premises indicating all adjacent properties and the nature of the business being carried out, on such premises
- A floor plan of the building in which the business premises are situated
- A plan of the actual layout of the business premises
- An inventory of equipment to be used in conducting the business
- A manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines, or scheduled substances or medical devices to be distributed and sold.

4.5 The application should specify the medicines, scheduled substances or medical devices to be distributed and sold.

4.6 The Council will only issue a WL when it is satisfied, usually following an inspection of a site by the designated Inspectors, that the information contained in the application is accurate and in compliance with requirements of the legislation and good wholesale or distribution practices.

4.7 Where appropriate, the MCC may refuse to grant a licence. In such cases the Registrar will notify the applicant to furnish the Council with such additional documentation or information as the Council may require. The notification will set out the reason for the proposal and give the applicant a reasonable period to respond. The applicant may make written representations. Before making a final decision on its proposal the MCC will take the applicant's written representation into consideration.

4.8 The legislative basis for the information required when applying for a WL may be found in the Medicines Act.

5 WHOLESALE DEALERS' OBLIGATIONS

5.1 The standard provisions for wholesale dealer's licences (WL) require a licence holder to:

(a) provide and maintain suitable staff, premises, equipment and facilities;

(b) provide information as requested by the MCC regarding the type and quantity of any medicinal product which he/she currently handles, stores or distributes;

5 Wholesale dealers' obligations continued

(c) inform the MCC of any proposed structural alterations to or discontinuance of use of premises to which the licence relates or which have been approved from time to time by the MCC;

(d) retain such transaction documents as are necessary to facilitate the withdrawal or recall of medicinal products;

(e) permit the MCC to carry out inspections, take samples or copies of documents;

(f) to have in place an emergency plan for the recall of medicinal products;

(g) to keep specified records as required by the Medicines Act that are available for inspection by the MCC for a period of five years after the date of receipt or dispatch;

(h) to appoint and designate a Responsible Pharmacist under whose personal supervision all activities take place;

(i) appoint and designate a natural person who resides in the Republic who shall be responsible to the Council for compliance with the Act;

(j) to obtain products only from licensed manufacturers whose licences relate to those products or from persons who are exempt from holding such licenses;

(k) apply for the renewal of the license every 5 years at least 90 days before the expiry of the existing licence.

6 THE RESPONSIBLE PHARMACIST

6.1 The Responsible Pharmacist (RP) is responsible for safeguarding product users against potential hazards arising from poor distribution practices – as a result, for example, of supplying suspect products, poor storage or failure to establish the *bona fides* of purchasers.

6.2 The RP must ensure that the conditions of the wholesale dealer's licence (WL) have been and are being complied with and that the guidelines on Good Wholesaling Practice (GWP) / Good Distribution Practice (GDP) are met. The MCC holds the licence holder accountable for breaches of the licence. However, if the RP is not adequately carrying out his/her duties, the MCC may consider the suspension of the licence, withdrawal of acceptance of the RP on that licence, and his/her acceptability on any other licence.

6.3 It is a statutory requirement that the RP be a pharmacist.

7 INSPECTION

7.1 The GMP Inspectorate carries out regular and repeated inspection of wholesale distribution sites. Inspections enable the MCC to confirm that licence holders are complying with the conditions of their licences, with the provisions of the Medicines Act and with Good Wholesaling Practice (GWP) / Good Distribution Practice (GDP).

7.2 Amongst other things, Inspectors are empowered to:

(a) enter any place or premises from which
- the holder of a licence to act as wholesaler or distibutor of medicines or medical devices

(b) Inspect the premises used in the storage and distribution of medicinal products and inspect any documentation or records relating to the storage and distribution of medicinal products

(c) take samples

7 Inspection continued

(d) seize any book, record, documentation or medicine, scheduled substances or medical devices.

It is required by legislation that licence holders shall make their premises available for inspection by the Inspectorate at any reasonable time.

7.2 Following an inspection, the Inspector prepares a report of his findings. A letter is sent to the licence applicant or holder noting any deficiencies found and asking for proposals to remedy them. In the event of serious non-compliance with GWP/GDP, the report is referred to the MCC for formal action, which can include the refusal, suspension or revoking of a licence.

8 POWERS TO SUSPEND OR REVOKE WHOLESALE / DISTRIBUTOR LICENCE

8.1 The MCC may revoke or suspend a licence when a statutory condition of that licence is no longer being met, the licence holder does not comply with the Act or if the RP fails to control the distribution of medicines, scheduled substances or medical devices.

8.2 The MCC will give the licence holder notice of its removal. The licence holder will be given 21 days to respond and give reasons why such licence should not be removed.

8.3 A licence holder or applicant may at any time within the period of 30 days from the date on which the decision is served on him appeal to the Minister to question the validity of the MCC's decision.

9 FEES

9.1 The Medicines Act introduced provisions for the payment of fees for licences, certificates and inspections. The current fees legislation for medicinal products is contained in the Medicines Regulations as amended.

9.2 Fees are currently payable for the following:

(a) Licence applications

(b) Licence renewal

(c) Licence issue

(d) Performance of inspections

An annual service charge is also payable during the currency of a licence.

9.3 A schedule of the current fees is available from the Registrar of Medicines or on the Medicines Control Council's website at www.MCCZA.COM.

9.4 When the MCC plans to make changes to the amount or frequency of fees, licence holders are consulted and given the opportunity to comment on the new fee proposals. Details of the new fees are published in the government gazette and on the Medicines Control Council's website at www.MCCZA.COM.

10 CONTACT DETAILS

The MCC and the Directorate: Inspectorate and Law Enforcement can be contacted at:

The Registrar
Medicines Control Council
Private Bag X828
PRETORIA
0001

APPENDIX 1

CONTROL AND MONITORING OF STORAGE AND TRANSIT TEMPERATURES

1.1 Good practise requires that wholesale dealers maintain storage areas within temperature limits appropriate for the product concerned and that temperatures are monitored regularly to demonstrate that specified storage conditions are met. It is also important that medicines are not subjected to adverse temperatures during delivery from warehouse to consumer. In some cases special arrangements may need to be made to protect the products during transit.

1.2 A wide variety of cold storage units are available, ranging from domestic refrigerators to large, custom-built, walk-in cold rooms. Whichever type of unit is used, it must be capable of maintaining all parts of the load within the range specified for the medicines concerned, which for products requiring cold storage is normally 2 – 8 °C. The type of temperature monitoring device used should be suitable for the type and size of the unit. As a guide, small units should be checked and recorded at least daily using a manual or electronic max./min. thermometer. Larger and walk-in units should be fitted with a continuous recording device such as a chart recorder, or a device that provides regular printouts of actual temperatures. These records should be checked at least daily and the checks should be recorded, e.g. by annotating the chart/printout. Measuring and recording devices should be calibrated regularly.

1.3 It is particularly important with large or walk-in units to be aware of the internal temperature distribution when they are in use. A temperature mapping exercise will identify hot and cold spots and will indicate the most appropriate position for temperature monitoring. Knowledge of the temperature distribution in a small unit is also important if it is regularly filled to capacity and it is not fan-assisted because, in these circumstances, products placed next to or in contact with a chiller plate or coil are likely to freeze and be permanently damaged. Temperature mapping should be performed annually and after any major change, unless multiple recording probes are employed for routine monitoring. If an alarm is fitted, it should be confirmed that it operates correctly at both its high and low set points, at least annually.

1.4 A small number of medicinal products need to be stored in a freezer. If these products are stored then temperature monitoring should demonstrate that the freezer is capable of maintaining the required temperature range. Temperature changes that may take place in the load during a defrost cycle should be known.

1.5 The extent of temperature monitoring employed within a warehouse will depend on the size and layout of the facility. For a small warehouse, the minimum requirement is that the maximum and minimum air temperatures are recorded at least daily using a thermometer placed in a strategic location.

APPENDIX 2

PERSONS WHO DO NOT REQUIRE A WHOLESALE DEALER'S LICENCE

2.1 The Holder of a certificate of Registration if the product has not left the premises of the licensed manufacturer or assembler before it is sold or supplied.

2.2 A person who holds a manufacturer's licence does not also need a wholesale dealer's licence in order to distribute those products to which the manufacturer's licence relates, but if any other products are distributed a wholesale dealer's licence is required.

2.3 Activities that are not wholesale distribution are therefore not licensed as such.

2.4 A pharmacist in a registered pharmacy, hospital or health centre, or someone acting under his supervision, who sells or supplies a medicinal product in accordance with a practitioner's prescription.

2.5 A group of persons who order goods jointly for subsequent retail sale by an individual.