MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

LICENCE TO ACT AS A WHOLESALER of MEDICAL DEVICES & IVDs

This guideline is intended to provide recommendations to wholesalers wishing to submit an application for a licence to act as a wholesaler of medical devices. It represents the Council's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. Alternative approaches may be used but these should be scientifically and technically justified. The Council is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance and that the wholesaler / distributor complies with acceptable quality assurance principles and good wholesale 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.

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 medical devices and IVDs for human and animal use, 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).

It is unlawful for medical devices or IVDs 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 Regulatory Authority.

The licensing process involves the Regulatory Authority, and the Directorate: Inspectorate and Law Enforcement, whose duties comprise the issue of licences to those engaged in the sale or supply of medical devices and IVDs by way of wholesale. Further, the Inspectorate and the Authority oversee the compliance of the licence holders with the provisions of their licences.

The wholesale or distribution of veterinary medical devices for animal use, registered with the Regulatory Authority 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 guideline is to provide guidance on the legislative requirements for the wholesale of medical devices and IVDs for human and animal use in terms of the provisions of the Act.

2 WHOLESALE

2.1 A wholesaler purchases medical devices or IVDs from a manufacturer or distributor and sells them into the retail sector.

2.2 All procuring, holding, supplying or exporting of medical devices and IVDs, apart from supplying medical devices and IVDs to the public, are wholesale activities.

2.3 The wholesale of unregistered medical devices and IVDs e.g. IVDs for Research Use Only (RUO) or investigational medical devices, or medical devices solely for export purposes, are also controlled.

2.4 In terms of Section 22H of the Act a wholesaler may not buy any medical device from any other source except from the original manufacturer or from the primary importer of the medical device, except when specifically exempted by the Director-General.

2.5 A person who holds a medical device or IVD manufacturer's or distributor's licence does not need a wholesale licence in order to distribute the medical devices to which the manufacturer's licence or distributor's licence relates.

2.9 However, if any medical device of which the company is not the HCR, is purchased from a third party for the purpose of distribution, a wholesale licence is required.

3 PERSONS REQUIRING A WHOLESALE LICENCE

Persons who in the course of a business are engaged in the wholesale of medical devices and IVD products for human and animal use require a wholesale licence.

4 HOW TO OBTAIN A LICENCE

4.1 Application forms for wholesale licences to act as a wholesaler of medical devices and IVDs are available from the Registrar or on the Regulatory Authority's website at www.mccza.com

4.2 An application for a wholesale licence should be accompanied by the prescribed application fee and in the case of a new Wholesaler, an inspection fee.

4.3 The application for a wholesale licence should include the qualification of staff to store, distribute and sell medical devices and IVDs, who should be able to comply with good wholesale practices as determined by Council.

4.4 The application should include:

- A quality manual of procedures and practices to be implemented to ensure the safety, quality and performance of medical devices and IVDs to be distributed and sold
- 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.

4.5 The application should specify the medical devices and IVDs to be distributed and sold.

4.6 The Regulatory Authority will only issue a wholesale licence when it is satisfied that the information contained in the application is accurate and the site is in compliance with requirements of good wholesale practices.

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

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

5 WHOLESALER'S OBLIGATIONS

5.1 The standard provisions for wholesale licences require a licence holder to:

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

(b) provide information as requested by the Regulatory Authority regarding the type and quantity of any medical device or IVD which he/she currently handles, stores or distributes;

(c) inform the Regulatory Authority 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 Regulatory Authority;

(d) retain such transaction documents as are necessary to facilitate the withdrawal or recall of medical devices and IVDs;

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

(f) to have in place an emergency plan for the recall of medical devices and IVDs;

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

(h) to appoint and designate an Authorised Representative under whose personal supervision all activities take place and who resides in the Republic and who shall be responsible to the Regulatory Authority for compliance with the Act;

(i) to obtain products only from licensed manufacturers or licensed distributors of medical devices or IVDs whose licences relate to those products;

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

6 THE AUTHORISED REPRESENTATIVE

"authorised representative" means a natural person, resident in the Republic of South Africa, who

(a) has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic;

(b) acts on behalf of a manufacturer, importer, distributor, wholesaler, retailer or service provider for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence or certificate of registration is issued; and

(c) is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations.

6.1 The Authorised Representative is responsible for safeguarding product users against potential hazards arising from poor wholesale and 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 Authorised Representative must ensure that the conditions of the wholesale licence have been and are being complied with and that the guidelines on Good Wholesaling Practice (GWP) / Good Distribution Practice (GDP) are met. The Regulatory Authority holds the licence holder accountable for breaches of the licence. However, if the Authorised Representative is not adequately carrying out his/her duties, the Regulatory Authority may consider the suspension of the licence, withdrawal of acceptance of the Authorised Representative on that licence, and his/her acceptability on any other licence.

7 CONTROL AND MONITORING OF STORAGE AND TRANSIT TEMPERATURES FOR MEDICAL DEVICES AND IVDs

7.1 Good practice requires that wholesalers of medical devices and IVDs 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 medical devices and IVDs are not subjected to adverse temperatures during delivery from warehouse to customer or user. In some cases, special arrangements may need to be made to protect the products during transit.

7.2 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 medical devices and IVDs 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.

7.3 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.

7.4 A small number of medical devices or IVDs 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.

7.5 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.

8 INSPECTION

8.1 The Inspectorate carries out inspections of wholesale sites. Inspections enable the Regulatory Authority to confirm that licence holders are complying with the conditions of their licences, with the provisions of the Act and with Good Wholesaling Practice (GWP) / Good Distribution Practice (GDP).

8.2 Amongst other functions, Inspectors are empowered to:

(a) enter any place or premises from which the holder of a licence to act as wholesaler of medical devices and IVDs;

(b) inspect the premises used in the storage and distribution of medical devices and IVDs and inspect any documentation or records relating to the storage and distribution of medical devices and IVDs;

(c) take samples;

(d) seize any book, record, documentation or medical device or IVD.

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

8.3 Following an inspection, the Inspector prepares a report of his findings. A letter is sent to the Wholesaler 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 Regulatory Authority for formal action, which can include the refusal, suspension or revoking of a licence.

9 POWERS TO SUSPEND OR REVOKE WHOLESALE LICENCE for MEDICAL DEVICES AND IVDs

9.1 The Regulatory Authority 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 Authorised Representative fails to control the distribution of medical devices and IVDs.

9.2 The Regulatory Authority 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.

9.3 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 Regulatory Authority's decision.

10 FEES

10.1 The Medicines and Related Substances Act, 1965 (Act 101 of 1965) introduced provisions for the payment of fees for licences, certificates and inspections. The current fees legislation for medicinal products is contained in the Regulations.

10.2 Fees are payable for the following:

(a) Licence applications

(b) Licence renewal

(c) Licence issue

(d) Performance of inspections

(e) annual retention fee

10.3 Fees payable to the Registrar are available on the MCC's website at www.mccza.com.

10.4 When the Regulatory Authority plans to make changes to the fees, stake 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 Regulatory Authority's website at www.mccza.com.

11 CONTACT DETAILS

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

The Registrar
Medicines Control Council
Private Bag X828
PRETORIA
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12 UPDATE HISTORY

Date	Reason for update	Version & publication
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