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Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-02

GUIDELINES ON CHANGE OF OWNERSHIP OF LICENSED AND APPROVED PREMISES

EFFECTIVE DATE:..... 19 / 01 / 2024

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19/01/2024

1.0 APPLICATION

These guidelines apply to change of ownership of premises approved or licensed by the Authority.

2.0 PURPOSE

The purpose of this guideline is to ensure the smooth transition of business operations from one owner to the next following the sale of the business to ensure that patients are not inconvenienced and continue to receive their medicines from those premises.

3.0 BACKGROUND / INTRODUCTION

Premises licences and permits are not transferable. Therefore, when a business changes ownership the premises should cease to operate until the new owner receives a licence or permit in their name to operate the business.

However, the Authority acknowledges the need for continuity of business operations to ensure that patients in the community are not inconvenienced and that they continue to receive a steady supply of their medicines. In that light, the Authority has in place a policy to manage the change of ownership of the business whereby businesses are allowed to transition smoothly from one owner to the next without cessation of operations as would be the consequence of following the prescribed legal processes.

It is important to note that this policy is a privilege and not a right, therefore it should not be abused.

4.0 DEFINITIONS

Change of ownership - this occurs when the business is transferred from one person or entity to another. The change of ownership is effective on the date that the Agreement of Sale between the seller and the buyer is signed unless the Agreement of Sale stipulates otherwise.

5.0 GUIDELINES

5.1 Submission of the Notification

The buyer and the seller are both required to complete a Notification of Change of Ownership form LEF 85 within five (5) days of signing of the Agreement of Sale. Attached to this form should be a certified copy of the Agreement of Sale which clearly indicates the date on which the transaction was made. If the form is not submitted to the Authority the former owner retains all legal obligations pertaining to the licensure of the business and will not be absolved of responsibility should the business

operations be found in contravention of the Medicines and Allied Substances Control Act (*Chapter 15:03*).

5.2 Documents required to process a temporary licence or permit for the new owner.

Within five (5) days of signing of the Agreement of Sale, the new owner is required to apply for the processing of a temporary licence or permit. The Authority will proceed to issue a temporary licence or permit to the new owner within two (2) working days from the date of submission. The temporary licence or permit will be valid for thirty (30) days. The documents to be submitted are as follows.

- 5.2.1 Completed Application form for issue of premises licence MC1 or Application for issue of a wholesale dealer's permit MC5.
- 5.2.2 Proof of payment of application fees as prescribed by the fee schedule.
- 5.2.3 Certified copy of the Agreement of Sale
- 5.2.4 Memorandum and Articles of Association (if a company)
- 5.2.5 CR14
- 5.2.6 Proof of citizenship or residence of company directors (e.g., certified copies of National Identity cards or passports)
- 5.2.7 Police clearance or affidavits of the company directors indicating that they have not within three (3) years preceding this application been convicted of an offence related to medicines of dishonesty.
- 5.2.8 Written conformation form the Pharmacists Council of Zimbabwe indicating compliance with the provisions of Section 124 of Health Professions Act (*Chapter 27:19*) (**Retail Pharmacies Only**)

5.3 Documents required to process a licence or permit valid for one year.

Once the temporary licence or permit is issued, the new owner will have thirty (30) days to submit documents for the issue of a licence or permit valid for a period of 12 months, commencing on the 1st of March (*for pharmacies*), 1st April (*for wholesalers*), 1st July (*for dispensing medical practitioners*) and 1st October (*for industrial clinics*) in each year. The inspection of the premises will be done once these documents have been submitted. The documents to be submitted are as follows.

- 5.3.1 Trading licence from the relevant Local Authority
- 5.3.2 Environmental health inspector's approval of premises (health report)
- 5.3.3 Floor layout of premises (*where the new owner intends to make material changes*)

5.4 Key considerations when seeking a buyer for a Pharmacy business.

- 5.4.1 When selling to a pharmacist or a partnership which comprises of pharmacists, be satisfied that the pharmacist(s) is/ are registered to practise.
- 5.4.2 When selling to a company, ensure that the company holds a compliance letter from the Pharmacists Council of Zimbabwe.

5.5 Processing of the application

- 5.5.1 Once all the requirements for 5.2 and 5.3 have been submitted to the Authority, inspector(s) will contact the applicant to schedule an appointment for the inspection of the premises to be licensed or approved.
- 5.5.2 The applicant can also make use of the checklist for inspection of the premises in preparation of the inspection found on the MCAZ website, www.mcaz.co.zw. Please note that all premises should meet all the minimum requirements for licensing as stipulated in the Third Schedule of the Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991 regardless of the premises being previously licensed.
- 5.5.3 Inspectors will write a report of the inspection conducted and it will be sent to the applicant within 48 hours of the inspection for premises in Harare and within 72 hours of return to the office for premises outside Harare. If there were any shortcomings which were noted during the inspection, the applicant will be required to respond to these shortcomings indicating how they have been rectified. In cases where structural shortcomings were noted during the inspection, a re- inspection of the premises will be required to verify the rectification of the shortcomings and a re- inspection fee as stipulated in the fee schedule + VAT shall be paid.
- 5.5.4 The licence or permit for the premises shall only be issued for those premises that have been inspected and found to be compliant. The licence or permit will be processed within two (2) working days of the premises being deemed compliant.
- 5.5.5 All matters pertaining to fulfilment of the requirements of the application should be resolved within sixty (60) days of submitting an application. Failure to resolve any outstanding issues within the stipulated time will result in the application being closed. Should the applicant wish to pursue the matter after the stipulated sixty (60) day period, a new application will have to be submitted.

5.6 CONTACT DETAILS

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6.0 KEY RELEVANT DOCUMENTS

6.1 Medicines and Allied Substances Control Act (*Chapter 15:03*)

6.2 Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991

6.3 Guidelines for Licensing of Premises and Persons

6.4 Application form for issue of premises licence MC1

6.5 Application for issue of a wholesale dealer's permit MC5

6.6 Notification of Change of Ownership Form LEF 85

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Date Reviewed: January 2024
0	July 2021	<p>Reason for Change and Amendments: System improvement</p> <p>Section 5.1 first sentence changed from The buyer and the seller are both required to complete a Notification of Change of Ownership form within five (5) days of signing of the Agreement of Sale</p> <p>Changed to The buyer and the seller are both required to complete a Notification of Change of Ownership form LEF 85 within five (5) days of signing of the Agreement of Sale</p> <p>Section 5.2 first sentence changed from Within five (5) days of signing of the Agreement of Sale, the new owner is required to submit an application for the processing of a temporary licence or permit.</p> <p>Changed to Within five (5) days of signing of the Agreement of Sale, the new owner is required to apply for the processing of a temporary licence or permit.</p>