MCAZ Medicines Control Authority of Zimbabwe

GUIDELINES FOR LICENSING OF PREMISES AND PERSONS

EFFECTIVE DATE: 29/6/2023

Medicines Control authority of Zimbabwe
106 Baines Avenue
P O Box 10559
Harare
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

Reviewed by:	..... Signature	28/06/2023 ..... Date
Checked by HoD/HoU:	..... Signature	28/06/2023 ..... Date
Approved by QM:	..... Signature	28/06/2023 ..... Date
Authorised by Director General:	..... Signature	29/6/2023 ..... Date

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1.0 APPLICATION

These guidelines apply to the licensing of persons and premises which include manufacturers, pharmacies, industrial clinics and dispensing medical practitioners. They also apply to the issuance of permits to wholesale dealers and VMGDs.

2.0 PURPOSE

To define;

2.1 The minimum requirements for the licensing and approval of premises;
2.2 The process to be followed when applying for a licence and/ or a permit for premises;
2.3 The requirements for the issue of a licence to a person;
2.4 Special requirements for medical practitioners;
2.5 The duration of licences and/ or permits;
2.6 Display of licences and or permits
2.7 Production and return of licences and/ or permits;
2.8 The application for renewal of licences and/ or permits;
2.9 Notification of any changes relating to licensed premises.

3.0 INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body which was established by an Act of Parliament, the Medicines and Allied Substances Control Act (MASCA) *(Chapter 15:03)*. In terms of Part VI of the Act, MCAZ is responsible for protecting public and animal health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality through the licensing and control of pharmaceutical premises and persons. The premises licensed by the Authority include manufacturers, pharmacies, industrial clinics and dispensing medical practitioners. The Authority also issues permits to wholesale dealers for the distribution of medicines and to Veterinary Medicines General Dealers (VMGDs) for the sale of veterinary medicines.

4.0 DEFINITIONS

4.1 **Authority:** means the Medicines Control Authority of Zimbabwe established by section 3 of MASCA;

4.2 **Director-General:** means the Director-General of the Authority appointed in terms of section 26 of MASCA;

4.3 **Dispense:** in relation to a medicine, means to *prepare*; or *count out*, *measure or decant from a bulk supply*; or *mix*; or *dissolve*; or *disperse*; and *dispose* of the medicine, for gain or otherwise, for the treatment of a particular person or animal but does not include the actual administration of the medicine.

4.4 **Inspector:** means a person appointed in terms of paragraph (*a*) of subsection (1) of section 65 of MASCA to be an inspector;

4.5 **Manufacture:** includes compound, process or pack for sale but does not include the compounding of a medicine by a medical practitioner, dental practitioner, veterinary surgeon or pharmacist if that medicine—

4.5.1 has not been advertised for sale in Zimbabwe; and

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4.5.2 does not contain any component the sale of which is prohibited by this Act; and

4.5.3 is supplied for the treatment of a particular person or animal;

4.6 **Medicine:** subject to section 75, means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in—

4.6.1 the diagnosis, treatment, mitigation or prevention of disease or any abnormal physical or mental state or the symptoms thereof in man or in animals; or

4.6.2 restoring, correcting or modifying any physical, mental or organic function in man or in animals.

4.7 **Pharmacist:** means a person registered as such under the Health Professions Act [*Chapter 27:19*];

4.8 **Veterinary medicine:** means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in—

4.8.1 the diagnosis, treatment, mitigation or prevention of disease or abnormal physical or mental state or the symptoms thereof in an animal; or

4.8.2 restoring, correcting or modifying any physical, mental or organic function in an animal.

5.0 GUIDELINES

5.1 PROCESS FOR APPLYING FOR A LICENCE AND/ OR A PERMIT FOR PREMISES

5.1.1 Applicants are encouraged to get a copy of these guidelines, read and understand them before securing a premises to be licensed.

5.1.2 Applicants are required to complete the relevant application forms. These can be obtained at the offices of the Director-General, Medicines Control Authority, 106 Baines Avenue, Harare, or can be downloaded from the Authority's website; www.mcaz.co.zw

The forms are as follows;

5.1.2.1 Application for issue of a licence for premises Form M.C.1 *(pharmacy, dispensing medical practitioner, veterinary surgeon, manufacturer, clinic)* http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=35:application-for-a-premises-licence&start=30

5.1.2.2 Application for the issue of a wholesale dealers permit Form M.C.5 http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=278:m-c-5-application-for-issue-of-a-wholesale-dealers-permit

5.1.2.3 Application for the issue of a permit to sell veterinary medicines Form M.C.11 http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=94:issue-of-vmgd-permit&start=10

5.1.3 The application fees are to be paid upon submission of the application. The fees are stipulated in the fee schedule and this can be downloaded from the MCAZ website.

5.1.4 Please note that the gazetted fees do not include VAT. The applicant is therefore required to add VAT to the fees.

5.1.5 The application should also be accompanied by the following documents;

5.1.5.1 A copy of the approved plans from the local Authority of the premises proposed to be licensed which shall comply with the requirements specified in the Fourth Schedule of the Medicines and Allied Substances Control (General) Regulations, S.I 150 of 1991;

5.1.5.2 In the case of an individual, certified proof of citizenship or proof of being ordinarily resident in Zimbabwe or proof of an exemption by the Minister; or

5.1.5.3 In the case of a company, proof of citizenship or proof of being ordinarily resident in Zimbabwe of the majority of directors or proof of an exemption by the Minister;

5.1.5.4 Floor layout of the premises drawn to a scale of 1:100;

5.1.5.5 Local authority approval for use or change of use of premises (Trading Licence);

5.1.5.6 Environmental Health Inspectors approval of premises (Health Report);

5.1.5.7 Memorandum and Articles of Association (if a company);

5.1.5.8 CR14 (if a company)

5.1.5.9 Affidavit(s) or police clearance for an individual or for company directors that they have not within the three (3) years preceding this application been convicted of any offence related to medicines of dishonesty.

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5.1.5.10 Written confirmation from the Pharmacist Council indicating compliance with the provisions of Section 124 of the Health Professions Act [Chapter 27:19] (**Retail Pharmacy Only**)

5.1.6 Once all the above requirements have been submitted to the Authority's offices, inspector(s) will contact the applicant to schedule an appointment for the inspection of the premises to be licensed.

5.1.7 Timeline for Inspection of a Premises;

5.1.7.1 Premises in Harare should be inspected within two (2) days from date of receipt of a complete application, where possible.

5.1.7.2 Premises outside Harare should be inspected within five (5) days from the date of receipt of a complete application, where possible.

5.1.8 The applicant can also make use of the checklists for inspection found on the MCAZ website www.mcaz.co.zw to prepare for the inspection. Depending on the type of premises, the applicant can also read the following guidelines;

5.1.8.1 Good Dispensing Practice Guidelines

5.1.8.2 Good Wholesaling Practice Guidelines

5.1.8.3 Guideline on Operation Of Industrial And Dispensing Clinics

5.1.8.4 Guidelines on Operating Veterinary Medicines General Dealers shops

5.1.8.5 Current World Health Organization (WHO) Good Manufacturing Practices (GMP) Guidelines

5.1.8.6 Guidelines for Setting up Local Pharmaceutical Production Sites in Zimbabwe

5.1.9 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.

5.1.10 The licence for the premises shall only be issued for those premises that have been inspected and found to be compliant. The licence will be processed within two (2) working days of the premises being deemed compliant.

5.1.11 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.

5.2 THE REQUIREMENTS FOR THE ISSUE OF A LICENCE TO A PERSON

5.2.1 Applicants are required to complete the application form for the issue of a licence to a person Form M.C.2
http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=50:issue-of-a-persons-licence&start=20

5.2.2 The application fees are to be paid upon submission of the application. The fees are stipulated in the fee schedule and this can be downloaded from the MCAZ website.

5.2.3 Please note that the gazetted fees do not include VAT. The applicant is therefore required to add VAT to the fees.

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5.2.4 The applicant is required to have passed the forensic examination set by the Authority; or to have satisfied the Authority that he is familiar with the regulations relating to the custody and dispensing of medicines and such other matter as the Authority may determine from time to time.

5.2.5 The Authority may exempt any person from the above requirement as stipulated in 5.2.4 if it is satisfied that such person has passed other examinations in the course of such person's studies or has such other practical experience as the Authority considers to justify the grant of such exemption.

5.2.6 The application should also be accompanied by the following documents;

5.2.6.1 Valid Practising Certificate from the relevant professional body

5.2.6.2 Proof of citizenship (*certified copies of national ID or passport*)

5.2.6.3 Affidavit or police clearance that you have not within the three (3) years preceding this application been convicted of any offence related to medicines of dishonesty.

5.2.7 Once a complete application for a licence for a person has been submitted, it will be processed within five (5) working days from the date of submission.

5.3 SPECIAL REQUIREMENTS FOR MEDICAL PRACTITIONERS

5.3.1 An application by a medical practitioner for a licence to dispense medicines from any premises in terms of section 55 of the Act shall not be granted where such premises are situated **within 5 kilometres** of a pharmacy.

5.4 DURATION OF LICENCES AND/ OR PERMITS

5.4.1 Any licence or permit, which is issued in respect of premises or persons, shall be valid for a **period of 12 months**, commencing in respect of

5.4.1.1 pharmacies, pharmacists and pharmacy technicians, on the **1st March**;

5.4.1.2 medical practitioners and dispensing medical practices, on the **1st July**;

5.4.1.3 nurses and industrial clinics, on the **1st October**;

5.4.1.4 wholesale dealers and sales representatives, on the **1st April**;

5.4.1.5 veterinary medicines general dealers. On the **1st January**; in each year, and may be renewed annually thereafter, before its expiry.

5.5 DISPLAY OF LICENCES AND/ OR PERMITS

5.5.1 A licensee or permit holder shall ensure that his licence or permit is prominently displayed at all times upon the licensed premises to which it relates.

5.5.2 Section 5.5.1 shall not apply in respect of any period during which the licence or permit is necessarily removed from the licensed premises concerned for the purposes of doing anything in terms of the Act or for any other lawful purpose the proof whereof, in any proceedings against any person for contravention of section 5.5.1, shall lie upon that person.

5.6 PRODUCTION AND RETURN OF LICENCES AND/ OR PERMITS

5.6.1 Whenever the Authority—

5.6.1.1 cancels any licence or revokes a permit; or

5.6.1.2 varies or amends the conditions of any licence or permit; or

5.6.1.3 imposes new conditions on the renewal of any licence or permit the Director-General shall request the holder of the licence or permit to produce such

licence or permit within such period as he may specify and the holder thereof shall produce such licence or permit within the specified period.

5.6.2 Any person who fails to comply with a request in terms of subsection 5.6.1 shall be guilty of an offence.

5.6.3 Whenever the Authority varies, amends or imposes any new conditions on any licence or permit, the Authority shall return such licence or permit duly endorsed to the holder thereof within a reasonable time.

5.7 APPLICATION FOR RENEWAL OF LICENCES AND/ OR PERMITS

5.7.1 An application for the renewal of a licence in terms of subsection (2) of section 60 of the Act shall be lodged with the Director-General, in triplicate, in **Form MC 3** for the renewal of a licence for premises and in **Form MC 4** for the renewal of a licence for a person—

5.7.1.1 before the expiry of such licence; and

5.7.1.2 shall be accompanied by the appropriate fee in respect of each licence.

5.7.1.3 The application shall be submitted through the Online platform and this can be accessed from the link below;

http://onlineservices.mcaz.co.zw/mcazonlineservices/OnlineUserLogin

5.7.1.4 Any person who wishes to renew his permit issued in terms of section *twenty-three of the regulations* shall make an application to the Director-General, and such application shall be accompanied by the appropriate fee. The application shall be submitted through the Online platform and this can be accessed from the link below;

http://onlineservices.mcaz.co.zw/mcazonlineservices/OnlineUserLogin

5.7.2 Where an application for the renewal of a licence or permit has been lodged with the Director-General, the validity of the licence or permit shall, where the applicant has not been given notice of the renewal or refusal of the application by the date of expiry of such licence, continue after the date of expiry until the decision of the Authority on the application is notified to the applicant by the Director-General.

5.7.3 Once a complete application for renewal is submitted, the renewal process shall be completed within a period of ten (10) working days from the date of submission of the application.

5.8 NOTIFICATION OF ANY CHANGES RELATING TO LICENSED PREMISES

5.8.1 All licence holders and permit holders are required to seek prior authorisation for any administrative or structural changes post licensure.

5.8.1.1 **Administrative amendment:** means an amendment to a permit or a licence which involves a change in trading name, composition of directors in a company, change in supervisor or qualified person etc. These changes do not require an inspection of the premises to be conducted. The Authority shall use form number LEF 97 which is a checklist for receiving applications for administrative amendments, highlighting the nature of the amendment.

5.8.1.2 **Structural amendment:** means any changes that are made to a licensed or approved premises post licensure. These include but are not limited to change in floor layout, change in flow of personnel and material in the plant, upgrade in HVAC, changes in the water system etc. The Authority shall use form number LEF 98 which

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is a checklist for receiving applications for structural amendments, highlighting the nature of the amendment.

5.8.1.3 **Manufacturing Amendment**: means any changes made by a licensed manufacturer that involves addition of a manufacturing activity other than that which was licenced and stated on the manufacturing licence **or** a cessation of a manufacturing activity which had been licenced and stated on the premises licence. These changes might require the premises to be inspected before licence amendment, depending on the nature of the manufacturing activity.

5.8.2 **Examples of administrative amendments**

5.8.2.1 **Change in the composition of directors**

Where the **composition of directors** has changed, the applicant is required to submit an updated CR14, and a compliance letter from the Pharmacists Council of Zimbabwe indicating compliance with the provisions of Section 124 of the Health Professions Act [Chapter 27:19]

5.8.2.2 **Change of Supervision**

Where there is change of supervision, the applicant is required to submit the completed application forms for issue of a premises and persons licence, the confirmation of supervision (LEF 26) and resignation letters.

5.8.2.3 Complete applications submitted for amendment shall be processed within a period of five (5) working days from the date of submission of the application.

5.8.3 **Examples of structural amendments**

5.8.3.1 Change of floor layout

An intention to change the floor layout of the premises shall be notified to the Director General in writing. The applicant shall be required to submit a copy of the proposed floor layout of the premises. The premises shall be inspected by inspectors to ensure that they are compliant and this will attract a fee as stipulated in the fee schedule. The proposed floor layout shall only be adopted once approval is received from the Authority.

5.8.4 **Examples of manufacturing amendments**

5.8.4.1 Addition of a manufacturing activity

An intention to change or addition of a manufacturing activity which was not in the scope of the manufacturing activities approved and licenced when the manufacturer set-up shall be notified to the Director General in writing. The applicant shall be a formal application letter stating the proposal as well as schematics if the additional manufacturing activity requires structural changes. The premises shall be inspected by inspectors to ensure that they are compliant, and this will attract a fee as stipulated in the fee schedule. For example, a manufacturer licensed to manufacture a particular dosage form intending to manufacture an additional dosage form which was not previously part of the initial licensure scope, would have to go through the licence amendment application process stated in the paragraph above.

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5.8.4.2 Cessation of a manufacturing activity

An intention to cease or discontinue a manufacturing activity which was in the scope of the manufacturing activities approved and licenced when the manufacturer set-up shall be notified to the Director General in writing. In such cases, the premises shall ordinarily not be inspected by inspectors to this sole purpose, unless circumstances warrant an inspection of the premises before officially ceasing the manufacturing activity. For example, a manufacturer licenced to manufacture sterile pharmaceutical products and general oral solid dosage forms decides to discontinue the production of sterile products for economic reasons, must notify the Director General so that the discontinued manufacturing activities are not included in the scope of the next routine inspection.

5.8.5 Other changes

5.8.5.1 Change of Ownership

Any change in the ownership of the business shall be made known to the Director General in writing. Please refer to the Guidelines for Change of Ownerships of Licensed and Approved Premises for detailed information. These are available on the MCAZ website, www.mcaz.co.zw

5.8.5.2 Relocation

An intention to change the **location** of the licensed or approved premises shall be made known to the Director General in writing. The applicant shall be required to go through the licensing process for the new premises as indicated under **section 5.1**.

5.9 SCENARIOS WHERE LICENCES OR PERMITS CAN BE CANCELLED OR SUSPENDED

5.9.1 A licence or permit can be **suspended** when a licence or permit holder is found with an offence in dealing with Dangerous Drugs.

5.9.2 A licence or permit can be **suspended** when there is failure to resolve critical issues noted during the inspection.

5.9.3 A licence can be **cancelled** due to the following offences;

i. Failure to provide continuous personal supervision of licenced premises.
ii. Selling medicines by wholesale without a wholesale dealer`s permit.
iii. Selling Unregistered Specified medicines.
iv. Selling of Expired Medicines.
v. Poor record keeping of Dangerous Drugs.
vi. Capturing insufficient patient details.
vii. Purchasing from Unlicensed Premises.
viii. Dispensing PP without prescriptions.

N.B These are only few examples but there can be cases in which the Authority can decide to suspend or cancel the licence apart from those that are listed.

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5.10 CONTACT DETAILS

Address: Medicines Control Authority of Zimbabwe
106 Baines Avenue
P.O Box 10559
Harare
Zimbabwe
Telephone number: 0242 736981-5; 708255; 2901327-31
Whatsapp number: 0718 855 932
Email addresses: mcaz@mcaz.co.zw

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 ICH Guideline Q12 on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

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7.0 HISTORY

DOCUMENT HISTORY		
Revision Number 0	Date Approved July 2020	Date Reviewed: 16/2/2022, Reviewed By: A.Verenga Reason for Change and Amendment Continuous Improvement and to Address GBT The following changes/amendments were done from Revision 1 to Revision 2
		Added 5.1.7 Timeline for Inspection of a Premises; 5.1.7.1 Premises in Harare should be inspected within two (2) days from date of receipt of a complete application, where possible. 5.1.7.2 Premises outside Harare should be inspected within five (5) days from the date of receipt of a complete application, where possible.
		Changed from 5.1.7.1 Good Dispensing Practice Guidelines Changed to 5.1.7.1 Premises in Harare should be inspected within two (2) days from date of receipt of a complete application, where possible .
		Changed from 5.1.7.2 Good Wholesaling Practice Guidelines Changed to 5.1.7.3 Premises outside Harare should be inspected within five (5) days from the date of receipt of a complete application, where possible.
		Changed from 5.1.8 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

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		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. Changed to 5.1.7 The applicant can also make use of the checklists for inspection found on the MCAZ website www.mcaz.co.zw to prepare for the inspection. Depending on the type of premises, the applicant can also read the following guidelines;
		(New)5.1.8.1 Good Dispensing Practice Guidelines
		(New)5.1.8.2 Good Wholesaling Practice Guidelines
		(New) 5.1.8.3 Guideline on Operation Of Industrial And Dispensing Clinics
		(New) 5.1.8.4 Guidelines on Operating Veterinary Medicines General Dealers shops
		5.1.8.5 Current World Health Organization (WHO) Good Manufacturing Practices (GMP) Guidelines
		Changed from 5.1.8 The licence for the premises shall only be issued for those premises that have been inspected and found to be compliant. The licence will be processed within two (2) working days of the premises being deemed compliant. Changed to 5.1.9 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.
		Change from 5.1.9 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. Changed to 5.1.10 The licence for the premises shall only be issued for those premises that have been inspected and found to be compliant. The licence will be processed within two (2) working days of the premises being deemed compliant.
		Changed from 5.7.1 An application for the renewal of a licence in terms of subsection (2) of section 60 of the Act shall be lodged with the Director-General, in triplicate, in Form MC 3 for the renewal of a licence for premises and in Form MC 4 for the renewal of a licence for a person— Changed to 5.7.1 An application for the renewal of a licence in terms of subsection (2) of section 60 of the Act shall be lodged with the Director-General, in triplicate, in Form MC 3 for the renewal of a licence for premises and in Form MC 4 for the renewal of a licence for a person—
		Changed from 5.7.1.3 The application forms can be downloaded from the links below;

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		http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=133:application-for-renewal-of-premises-license&start=30 http://www.mcaz.co.zw/index.php/downloads/category/10-application-forms?download=92:renewal-of-persons-licence&start=20 Changed to 5.7.1.3 (New) The application shall be submitted through the Online platform and this can be accessed from the link below; http://onlineservices.mcaz.co.zw/mcazonlineservices/OnlineUserLogin
		5.7.1.4 (New) Any person who wishes to renew his permit issued in terms of section twenty-three of the regulations shall make an application to the Director-General, and such application shall be accompanied by the appropriate fee. The application shall be submitted through the Online platform and this can be accessed from the link below; http://onlineservices.mcaz.co.zw/mcazonlineservices/OnlineUserLogin
		5.8.1 (New) All licence holders and permit holders are required to seek prior authorisation for any administrative or structural changes post licensure.
		5.8.1.1(New) Administrative amendment: means an amendment to a permit or a licence which involves a change in trading name, composition of directors in a company, change in supervisor or qualified person etc. These changes do not require an inspection of the premises to be conducted.
		5.8.1.2(New) **Structural amendment:** means any changes that are made to a licensed or approved premises post licensure. These include but are not limited to change in floor layout, change in flow of personnel and material in the plant, upgrade in HVAC, changes in the water system etc.
		Changed from 5.8.2 Change of Ownership Please refer to the Guidelines for Change of Ownerships of Licensed and Approved Premises for detailed information. These are available on the MCAZ website, www.mcaz.co.zw Changed to 5.8.2 **Examples of administrative amendments** 5.8.2.1 (New) Change in the composition of directors Where the composition of directors has changed, the applicant is required to submit an updated CR14, and a compliance letter from the Pharmacists Council of Zimbabwe indicating compliance with the provisions of Section 124 of the Health Professions Act [Chapter 27:19]

		5.8.2.2 (New)Change of Supervision Where there is change of supervision, the applicant is required to submit the completed application forms for issue of a premises and persons licence, the confirmation of supervision (LEF 26) and resignation letters.
		Changed from 5.8.3 Change in the composition of directors Where the composition of directors has changed, the applicant is required to submit an updated CR14 and a compliance letter from the Pharmacists Council of Zimbabwe indicating compliance with the provisions of Section 124 of the Health Professions Act [Chapter 27:19] Changed to 5.8.3 Examples of structural amendments
		5.8.3.1 (New) Change of floor layout An intention to change the floor layout of the premises shall be notified to the Director General in writing. The applicant shall be required to submit a copy of the proposed floor layout of the premises. The premises shall be inspected by inspectors to ensure that they are compliant and this will attract a fee as stipulated in the fee schedule. The proposed floor layout shall only be adopted once approval is received from the Authority.
		Changed from 5.8.4 An intention to change the floor layout of the premises shall be notified to the Director General in writing. The applicant shall be required to submit a copy of the proposed floor layout of the premises. The premises shall be inspected by inspectors to ensure that they are compliant and this will attract a fee as stipulated in the fee schedule. The proposed floor layout shall only be adopted once approval is received from the Authority. Changed to 5.8.4 Other changes
		5.8.4.1(New) Change of Ownership Any change in the ownership of the business shall be made known to the Director General in writing. Please refer to the Guidelines for Change of Ownerships of Licensed and Approved Premises for detailed information. These are available on the MCAZ website, www.mcaz.co.zw
		5.8.4.2 (New) Relocation

		An intention to change the location of the licensed or approved premises shall be made known to the Director General in writing. The applicant shall be required to go through the licensing process for the new premises as indicated under section 5.1.
		Changed from 5.9 CONTACT DETAILS Address: Medicines Control Authority of Zimbabwe 106 Baines Avenue P.O Box 10559 Harare Zimbabwe Telephone number: 0242 736981-5; 708255; 2901327-31 Whatsapp number: 0718 855 932 Email addresses: mcaz@mcaz.co.zw Changed to 5.9 SCENARIOS WHERE LICENCES OR PERMITS CAN BE CANCELLED OR SUSPENDED
		5.9.1 (New) A licence or permit can be suspended when a any licence or permit holder is found with an offence in dealing with Dangerous Drugs.
		5.9.2 (New) A licence or permit can be suspended when there is failure to resolve critical issues noted during the inspection.
		5.9.3 (New) A licence can be cancelled due to the following offences; i. Failure to provide continuous personal supervision of licenced premises. ii. Selling medicines by wholesale without a wholesale dealer`s permit. iii. Selling Unregistered Specified medicines. iv. Selling of Expired Medicines. v. Poor record keeping of Dangerous Drugs. vi. Capturing insufficient patient details. vii. Purchasing from Unlicensed Premises. viii. Dispensing PP without prescriptions.
		N.B These are only few examples but there can be cases in which the Authority can decide to suspend or cancel the licence apart from those that are listed.
1	February 2022	Reason for Change and Amendment Continuous Improvement and to Address GBT Requirements

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		The following changes/~~amendments~~ were done from Revision 1 to Revision 2
		Added 5.1.8.6 Guidelines for Setting up Local Pharmaceutical Production Sites in Zimbabwe
		Added 5.7.3 Once a complete application for renewal is submitted, the renewal process shall be completed within a period of ten (10) working days from the date of submission of the application.
		Added 5.8.1.1 The Authority shall use form number LEF 97 which is a checklist for receiving applications for administrative amendments, highlighting the nature of the amendment.
		Added 5.8.1.2 The Authority shall use form number LEF 98 which is a checklist for receiving applications for structural amendments, highlighting the nature of the amendment.
		Added 5.8.1.3 **Manufacturing Amendment**: means any changes made by a licensed manufacturer that involves addition of a manufacturing activity other than that which was licenced and stated on the manufacturing licence **or** a cessation of a manufacturing activity which had been licenced and stated on the premises licence. These changes might require the premises to be inspected before licence amendment, depending on the nature of the manufacturing activity.
		Added 5.8.2.3 Complete applications submitted for amendment shall be processed within a period of five (5) working days from the date of submission of the application.
		Added 5.8.4 **Examples of manufacturing amendments** **5.8.4.1 Addition of a manufacturing activity** An intention to change or addition of a manufacturing activity which was not in the scope of the manufacturing activities approved and licenced when the manufacturer set-up shall be notified to the Director General in writing. The applicant shall be a formal application letter stating the proposal as well as schematics if the additional manufacturing activity requires

		structural changes. The premises shall be inspected by inspectors to ensure that they are compliant, and this will attract a fee as stipulated in the fee schedule. For example, a manufacturer licensed to manufacture a particular dosage form intending to manufacture an additional dosage form which was not previously part of the initial licensure scope, would have to go through the licence amendment application process stated in the paragraph above.
		Added **5.8.4.2 Cessation of a manufacturing activity** An intention to cease or discontinue a manufacturing activity which was in the scope of the manufacturing activities approved and licenced when the manufacturer set-up shall be notified to the Director General in writing. In such cases, the premises shall ordinarily not be inspected by inspectors to this sole purpose, unless circumstances warrant an inspection of the premises before officially ceasing the manufacturing activity. For example, a manufacturer licenced to manufacture sterile pharmaceutical products and general oral solid dosage forms decides to discontinue the production of sterile products for economic reasons, must notify the Director General so that the discontinued manufacturing activities are not included in the scope of the next routine inspection.