Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-04

GUIDELINES ON OPERATIONS OF INDUSTRIAL AND DISPENSING CLINICS

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Medicines Control authority of Zimbabwe

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1.0 APPLICATION

These guidelines apply to Industrial and Dispensing Clinics that are licensed by the MCAZ.

2.0 PURPOSE

To a target or specific population of an organisation (i.e. employees of companies and/or their dependants / students and/or staff members of a school, college or university / research participants/patients of a research clinic).

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) licenses industrial and dispensing clinics to provide dispensing services to a target or specific population of an organisation (i.e. employees of companies and/or their dependants / students and/or staff members of a school, college or university / research participants/patients of a research clinic).

In most instances qualified state registered nurses are employed to run the clinics. The nurses therefore attend to the patients and depending on the patients' needs, dispense medicines from these clinics. As nurses are not prescribers in terms of the Medicines and Allied Substances Control (General) Regulations, 1991, (SI 150 of 1991) (hereafter referred to as "the Regulations"), some of the clinics employ qualified Medical Practitioners to provide medical services. The Medical Practitioner may therefore be employed on a part-time or full- time basis depending on the clinic's circumstances and requirements for services.

The purpose of these guidelines is therefore to define the responsibilities expected of the medical practitioner and nurse employed at an industrial and/or a dispensing clinic licensed by the MCAZ. The guidelines will also provide conditions under which the clinics may be licensed.

4.0 DEFINITIONS

4.1 Industrial and/or a dispensing clinic

It can be any of the following:

4.1.1. Can be a clinic providing health services to employees and/or dependants of employees of a particular company or a group of affiliated companies.

4.1.2. Can be a clinic providing health services to students and staff members of a school, college or university.

4.1.3. Can be a research clinic providing health services to a target / specific population.

4.2 **Dispensing:** in relation to medicines is the preparation, packaging, labelling, record keeping, and transfer of a prescription drug to a patient or an intermediary, who is responsible for administration of the drug.

4.3 **Affiliated companies**: more than one company that belong to the same corporate holding or have written contractual arrangements with a common provider of health services. Companies pooling resources for the purpose of providing clinical services for their employees only are included. Specific clinics with unique settings may be granted authority to provide services to dependants.

5.0 GUIDELINES

5.1 Application requirements for a premises licence for an industrial and dispensing clinic

5.1.1 An industrial and dispensing clinic must be licensed as such, by the Medicines Control Authority of Zimbabwe according to the MASCA 15:03.

5.1.2 The requirements for an application for the issue of an industrial and dispensing clinic are as listed below:

5.1.2.1 Application form for the issue of a premises licence (M.C.1).

5.1.2.2 HPA approval for use of the premises.

5.1.2.3 Proof of citizenship or residence for the company directors if a company (majority of directors should be Zimbabweans or ordinarily resident in Zimbabwe).

5.1.2.4 Proof of citizenship or residence for the school head or principal if the clinic is for a school or college.

5.1.2.5 Application fees are accessible on our website https://www.mcaz.co.zw/documents/approved-fees/fee-schedule/

5.1.2.6 Environmental Health Inspectors approval of the premises (Health Report) from the Local Authority.

5.1.2.7 Complete and current CR14 if the clinic is for a company.

5.1.2.8 Affidavits or police clearance for company directors or school head that they have not within the (3) years preceding the application, been convicted of any offence related to medicines or dishonesty.

5.2 Application requirements for a person's licence for a dispensing nurse

5.2.1 These requirements apply to a registered general nurse who is to be employed or employed at a specified company / school / college, with a clinic which falls within the category of industrial and dispensing clinics. The supervisor for an industrial / dispensing clinic should be licensed as such by the Medicines Control Authority of Zimbabwe according to the MASCA 15:03.

5.2.2 The requirements for such an application are as listed below:

5.2.2.1 Application form for issue of a person's licence (M.C.2).

5.2.2.2 Valid practicing certificate for a registered general nurse from the Nurses Council of Zimbabwe.

5.2.2.3 Copy of Letter from HPESS (Health Professions Education and Student Support) that states that they have sat for the forensic examination and passed.

5.2.2.4 Proof of citizenship or residence for the registered general nurse (**Certified**).

5.2.2.5 Affidavits or police clearance for the supervisor to be that they have not within the (3) years preceding the application been convicted of any offence related to medicines or dishonesty.

5.3 Operational Requirements

5.3.1 To comply with the requirements of the Regulations or any other requirements set by the MCAZ from time to time.

5.3.2 To have operating times clearly displayed at all times and indicating the doctor's attendance times.

5.3.3 For a clinic to be licensed it should be intended to provide services to at least 30 persons (i.e. a catchment of not less than 30 persons) excluding contract employees.

5.3.4 Services to be provided only to employees of one company or a group of affiliated companies and/or their dependants or to school children or students, of a school or a college.

5.3.5 An independently operated clinic that is contracted by more than one company to provide services may be licensed provided evidence of the written contractual arrangements is provided, and motivation for approval of the service provision is provided from each company to be provided with the services. The contract must, amongst other matters, indicate the expected beneficiaries i.e. employees and their dependents only, their numbers and that the clinic will be expected to comply fully with these guidelines.

5.4 Classes of Clinics and Categorization of Medicines

5.4.1 Human medicines fall into six (6) categories of medicines for distribution as indicated by their registration details on the labels. The medicines that may be prescribed at industrial and dispensing clinics will be determined by the MCAZ on the following classification. The particular clinic classification will be stated on the premises licence:

5.4.1.1 **Class A Clinic**

i. Is a clinic where there is a supervising medical practitioner all the times that the clinic is open; all categories of medicines can be dispensed.

ii. **N**-narcotics, **PP**-prescription preparation, **PP10**-prescription preparation tenth schedule, **PIM**-pharmacist initiated medicines, **P**-pharmacy medicine and **HR**-household remedies.

5.4.1.1 **Class B Clinic**

i. Is a clinic where there is a supervising medical practitioner as specified in section **5.5** below, all categories of medicines can be dispensed when the medical practitioner is present.

ii. No **PP**, **PP10**, **PIM** category medicines to be dispensed in the absence of the supervising medical practitioner.

iii. **P.S** In the case of an emergency **PP**, **PP10**, **PIM** category medicines can be dispensed, only if the prescription has been obtained through the phone and is documented as such. Thereafter a written prescription should be obtained from the stationed visiting medical practitioner. Countersigning of prescriptions after the fact is also only permitted only in cases of emergency when the conditions in **5.5.6** below apply.

5.4.1.2 **Class C Clinic**

i. Is a clinic where there is no supervising medical practitioner.

ii. nly Household Remedy (**HR**) and Pharmacy Only **(P)** categories can be dispensed from such clinics.

5.4.1.3 **Class D Clinic** (Restricted Industrial and Dispensing Clinic)

i. Covers institutions like research clinics, all non-governmental research centres, universities clinics and boarding schools. Medicines dispensed at a Class D clinic fall under the same categories as Class A, Class B and Class C depending on the situation at hand (i.e. either there is a permanent residing doctor, visiting doctor or no doctor at all).

5.4.2 A licensed clinic should **not** supply medicines for use at any other premises **including** other clinics **except** those of affiliate companies;

5.4.3 The supervising medical practitioner's surgery even if they hold valid licences or permits.

5.4.4 Should the clinic have more than one nurse dispensing medicines from the clinic, be it for a few hours a day, the nurse should have attended and obtained the forensic training and his/her name should appear on the premises' licence.

5.4.5 In the case where a clinic is operated on behalf of a company or affiliated companies, access to the medicines by those persons not appearing on the clinic's licence is prohibited, particularly when the approved supervisors are not on the premises.

5.5 Requirements for Supervising Medical Practitioners

5.5.1 Should be a holder of a valid unrestricted practising certificate from the Medical and Dental Practitioners Council of Zimbabwe.

5.5.2 Should be approved by MCAZ as supervising medical practitioner. In the case of a medical practitioner who is employed in the Public Service, Local Authority or Defence forces on a full time basis, prior written permission from the Secretary for

Health and Child Welfare or respective Director of Medical Services to engage in such practice, should be obtained respectively.

5.5.3 Is to visit the clinic not less than once a week for a period of not less than 2 hours per visit. This condition can be superseded only in circumstances stated to the Authority in writing and approved thereof.

5.5.4 Is to ensure proper records are kept for all PP and PIM medicines.

5.5.5 Is to ensure that medicines that require a prescription (including PIM) are dispensed by licensed persons endorsed on the clinics' licence only, on the basis of the Medical Practitioner's written instructions i.e. a prescription.

5.5.6 In the case of an emergency, the Medical Practitioner should order the medicine over the phone on the condition that he/she provides a prescription or records his instruction in writing within seven days thereof; when the nurse effects the order they should indicate on the dispensing records that it was an emergency and what the nature of the emergency was.

5.5.7 Should the Medical Practitioner cease to be the supervising medical practitioner for that clinic he/she should notify the MCAZ in writing within seven days of cessation of provision of those services.

5.5.8 Should the Medical Practitioner fail to comply with the above he/she will be held liable for all the activities supposedly under his control at the clinic until or unless the notification is received in writing by the MCAZ.

5.5.9 Any Medical Practitioner who knowingly makes a false declaration in any way to the MCAZ that they are the supervising medical practitioner of any clinic when they are not, will be liable for prosecution.

5.5.10 Should the supervising medical practitioner be unavailable to provide services for more than one month, he/she may make arrangements for another medical practitioner to cover for her or him provided that:

5.5.10.1 He/she complies with requirements of Sections **5.5.1, 5.5.2, 5.5.3, 5.5.4, 5.5.5, 5.5.6** and **5.5.10** of these guidelines.

5.5.10.2 The period of absence is not more than one calendar months in which instance prior written approval should be sought from the MCAZ.

5.5.11 The supervising medical practitioner should ensure that;

5.5.11.1 Medicines are only handled by approved and qualified persons and that these guidelines and relevant statutes are adhered to.

5.5.11.2 Access to the medicines is restricted to those people whose names are endorsed on the clinic licence.

5.5.10.3 The supervising medical practitioner and those other persons with names endorsed on the licence are responsible for reporting to the MCAZ any changes to the conditions under which the licence was issued, any deviations (intended or otherwise).

5.5.10.4 Loss of medicines due to theft must be reported to the MCAZ and the Police within twenty-four hours.

5.5.11.5 A Medical Practitioner may supervise more than one clinic provided the clinics are within reasonable distance to allow for the minimum visiting times indicated in section **5.5.3**

5.6 Requirements for Supervising Nurses

5.6.1 Holder of a valid unrestricted practising certificate from the Zimbabwe Nurses Council as a Registered General Nurse.

5.6.2 Should have attended the Forensic Lectures at HPESS (Health Professions Education and Student Support) and should have passed the forensic examination.

5.6.3 Should be licensed with MCAZ to dispense medicines at that particular clinic (valid person's licence)

5.6.4 In case a nurse is granted authority by the MCAZ to supervise more than one clinic the times of attendance will be stipulated on their person's licence.

5.6.5 To only dispense categories of medicines appearing on the clinic's licence.

5.6.6 To dispense only those categories of medicines stipulated on the clinics licence as described in section **5.4.**

5.6.7 Should the registered nurse be unavailable to provide services for less than or equal to one month, he/she may make arrangements for a registered nurse either licensed with MCAZ or non-licensed to cover for her or him provided that he/she complies with requirements of Sections 8.6.1, 8.6.2 and 5.6.6 respectively of these guidelines

5.6.8 If the period of absence of the supervising nurse is more than one calendar month, written prior approval should be sought from the MCAZ and he or she may make arrangements for another licensed registered nurse to cover for him or her provided that he/she complies with requirements of Sections **8.6. 1, 8.6. 2** and **5.6.6** of these guidelines.

5.6.9 In the event of an emergency and the Medical Practitioner makes a verbal order to the nurse for medicine to be made available to a patient, the nurse should indicate on the industrial and dispensing records that it was an emergency and the nature of the emergency.

5.6.10 To ensure that only registered medicines procured from premises licensed by MCAZ are used at the premises and adequate records of use are kept.

5.6.11 To ensure that no expired medicines are presented for sale.

5.6.12 To conduct regular stock control of all medicines the nurse dispenses, administers, disposes of. To ensure that medicines are dispensed with the appropriate labelling, in appropriate containers and under appropriate conditions of Good Dispensing Practice.

5.6.13 Should the nurse cease to be employed at that clinic the nurse should notify the MCAZ in writing within seven days of cessation of provision of those services and ensure that the employer does so too.

5.6.14 Should the nurse fail to comply with the above they will be held liable for all activities supposedly under their control until or unless the notification is received in writing.

PS: Nurses that already hold valid person's licences should attend a refresher course every three years from date of issue or attending the Forensic Lecture.

5.7 Building

5.7.1 The building should be free of rodents, vermin, birds and pests.

5.7.2 It should provide protection for the medicines from contamination and deterioration, including heat, direct sunlight and moisture.

5.7.3 It should be clean and maintained in a good state of repair to prevent ingress of soil and dust and rain.

5.7.4 The building should have sufficient security to prevent misappropriation of medicines.

5.7.5 The dispensing and storage areas of medicines should have adequate shelving fitted for the storage medicines.

5.7.6 The floors and dispensing tables should have a smooth and impervious finish.

5.8 Sale of Medicines

5.8.1 Industrial and dispensing clinics are only allowed to purchase medicines from approved, licensed premises namely manufacturers and wholesale dealers in Zimbabwe.

5.8.2 Clinics will have to seek assistance from authorised wholesalers for importation of any medicine

5.8.3 Industrial and dispensing clinics are expected to have on site a copy of the current updated premises register to facilitate in the purchasing of medicines from approved premises, a current and updated register for human medicines for reference on registered medicines.

NB: The sale of unregistered medicines is not allowed {Ref: Medicines and Allied Substance Control Act Section 29 1a}.

5.8.4 The sale of expired medicines is not allowed. All medicines should be returned to the manufacturer, distributor or wholesaler at least 3 months before expiry. Should the medicines expire, they should be removed from shelves and organise for destruction.

5.8.5 Pre-packed medicines should have the clinic details as well as sufficient details of the original packaging of the medicines (these details include batch numbers and expiry dates of medicines).

5.8.6 All dispensed prescription preparations shall be labelled with-

5.8.6.1 The registered name, strength and form of the medicine;

5.8.6.2 The total quantity of the medicine

5.8.6.3 The directions for use

5.8.6.4 Any warnings

5.8.6.5 The name of the patient

5.8.6.6 The name of the prescriber

5.8.6.7 The name of the manufacturer

5.8.6.8 The prescription reference number allocated to the prescription by the person dispensing the medicine

5.8.6.9 The date on which the prescription preparation is supplied

5.8.6.10 The name and address of the supplier.

5.8.7 The dispensing nurse shall on the day on which a prescription preparation is supplied or dispensed or, if that is not reasonably practicable, on the business day next following that day, record in a manner acceptable to the Authority, a complete copy of the prescription.

5.8.8 Records of dispensing shall be kept for a period of 5 years and shall be preserved such in the clinic where the dispensing took place provided that where the premises cease to be used or licensed, the nurse shall make arrangements, acceptable to the Authority, for the preservation or destruction of the records.

5.9 Handling of Cold Chain Products

5.9.1 Medicines must be kept within the correct environmental storage conditions.

5.9.2 Cold chain products mainly vaccines must be stored in a cold room / refrigerator at temperatures between +2 and +8°C and must not be frozen.

5.9.3 The cold chain storage facilities must be monitored by placing a temperature monitoring device inside the cold room / refrigerator and record the temperatures on a tally sheet at least once in the morning and once in the afternoon.

5.9.4 Delivery of cold chain products from wholesale dealers must be done using a refrigerated car or cooler boxes with ice packs or other cooling agents.

5.9.5 Clinics that keep cold chain products should have means of backup power supply in case of power cuts.

5.9.6 Clinics keeping cold chain products e.g. vaccines, must also supply a means of maintaining cold chain e.g. ice packs.

5.10 Documentation and Records

5.10.1 Invoices obtained from suppliers (Manufacturers / Wholesale dealers) of human medicines must be kept on site.

5.10.2 Inspectors may request to see the invoices to establish that all medicines procured are being sourced from approved suppliers as is prescribed in section 17A of the SI 150 of 1991.

5.11 Contact Details

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Telephone number: 0242 736981-5; 708255; 2901327-31, 0772 145 191

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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 Good Dispensing Practices Guidelines

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	**Date Written**: January 2018
Rev 1	January 2018	**Description of changes** Rolling Review and Documenting the guideline in a standard template **Revision status** **Uncontrolled version** Rev 1_ January 2018 to **Controlled** template Revision 0_ June 2022