INFORMATION MANUAL

JUNE 2023

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1. 0. Introduction

Pharmacy and Medicines Regulatory Authority (PMRA) is a statutory organisation established by the PMRA Act No. 9 of 2019 with the primary mandate of regulating the pharmaceuticals as well as the related allied substances such as Acaricides, Cosmetics, disinfectants, food Supplements, feed additives and supplements, traditional medicines, medical and surgical sundries, medical devices, reagents, and condoms, in Malawi. PMRA secretariat, led by the Director General, operates under the direct supervision of the Authority, which is appointed by the Minister of Health. PMRA's offices are conveniently located in Lilongwe, specifically off Paul Kagame/ Chilambula road in area 5, at plot number 50/50.

1.1. Mission

To safeguard the health of the population of Malawi through assurance of the quality, safety, and efficacy of medicines and allied substances; and enforcement of the standards of the pharmacy practice.

1.2. Vision

The trusted and independent regulator of medicines, allied substances and the pharmacy profession in Malawi.

1.3. Core Values

1. Professionalism – We are competent, highly motivated and result oriented.
2. Client-centrism - We are customer centred and communicate openly and in time manner.
3. Team work – We embrace collaboration and partnership within and without.
4. Integrity – We are confidential, honest, accountable and transparent.
5. Innovation – We continuously learn and improve.

2.0. Access to Information Act (ATIA of 2017)

The Access to Information Act (ATIA) of 2017 provide for the right of access to information in the custody of public bodies and relevant private bodies; the processes and procedures related to obtaining that information; and to provide for matters connected therewith or incidental thereto.

The Act stipulates that information holders should develop an information manual. This manual is designed to ensure that there is consistency in the provision of information under the custody of PMRA.

3.0. Objectives of the Information Manual

1. To provide a catalogue of information in the custody of PMRA
2. To comply with the requirements of the ATIA.

4.0. Core Functions of the PMRA

1. Regulate and control the manufacture, clinical trials, marketing authorization, importation, exportation, distribution and sale of medicines and allied substances and veterinary products.
2. Inspect any premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances for any other purpose regulated under the PMRA Act.
3. Regulate and control the advertising and promotion of medicines and allied substances.
4. Register and regulate pharmacy practice, premises, personnel and their training.
5. In consultation with relevant professional bodies, establish, maintain and develop standards for the operation of pharmacy practice premises and the pharmacy profession in general.
6. Approve the use of unregistered and unauthorised medical products for trial or for compassionate use.
7. Establish functional system for pre and post marketing surveillance of safety, quality, efficacy and effectiveness of medical products and to optimize the risk benefit balance.
8. Establish, maintain and enforce standards for medicine quality control laboratories.
9. Formulate, disseminate and advise the minister on policies relating to regulation and control of medicines and allied substances.
10. Continually review rules, regulations, guidelines and procedures pertaining to the implementation of the PMRA Act and make amendments where necessary in order to keep pace with changing dates and pharmaceutical industry demands.

11. In consultation with relevant research institutions, determine national priorities in pharmaceutical research.

5.0 Key Departments

The PMRA has the following functional departments:

5.1. Medicine Registration Department

Registration department is responsible for planning and implementation of pre-market product assessment and post-market quality and safety monitoring to ensure access to medicines that meet set standards at all times.

5.2. Inspectorate and Law Enforcement Department

The inspectorate and law enforcement department ensures that pharmaceutical premises, personnel and medicinal products meet the minimum standards as specified in the PMR Act and regulations through regular and scheduled inspection activities.

5.3. Quality Control Laboratory

The National Medicine Quality Control Laboratory (NMQCL) is established under Section 79 of the PMR Act. It aims at providing effective support to the Authority, making sure that analytical test results obtained accurately describe the properties of the samples assessed, permitting correct conclusions to be drawn about each medicine and also serving as an adequate basis for any subsequent regulatory decision and legal action.

5.4. Human Resource and Administration Department

The Human Resource and Administration Department is responsible for anchoring all functions of the Authority. The Department oversees the acquisition of human resources, development and their retention. Administratively, the department is responsible for ensuring that adequate assets, equipment and materials are procured and are in place.

5.5. Finance

The Finance Department is responsible for providing the financial and management accounting for the Authority.

6.0. Information for Disclosure

This section provides categories of information that the public can access from the PMRA in accordance with the ATIA.

6.1. Act & Regulations:

i. Pharmacy and Medicines Regulatory Authority Act (No. 9 of 2019)
ii. Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2022.
iii. Pharmacy, Medicines and Poisons Regulations, 1998

6.2. Guidelines & Policies:

i. A Guide to Pharmacy Personnel Registration in Malawi
ii. Guidelines for Importation & Exportation of Products
iii. Minimum Requirements for Veterinary Medicines Store
iv. Minimum Requirement for Dispensing Premises
v. Minimum Requirement for Medical Device Wholesaler
vi. Minimum Requirements for Human Medicine Store
vii. Minimum Requirements for Retail Pharmacy
viii. Good Distribution Practices for Pharmaceutical Products
ix. Guidelines on Recall of Medicines for Distribution System
x. Malawi Guidelines for Destruction of Medicines and Allied Substances
xi. Guidelines on Advertisement and Promotion of Medicines and Allied Substances
xii. Strategic Plan
xiii. Communication Strategy

6.3. Application Forms:

i. Wholesale Pharmacy and Application Form
ii. Wholesale Pharmacy Relocation Form
iii. Retail Pharmacy Application Form
iv. Retail Pharmacy Relocation Form
v. Dispensing License Application Form
vi. Relocation Form for Dispensing License
vii. Manufacturing License Application Form
viii. Relocation Form for a Pharmaceutical Manufacturer
ix. Pharmacy Personnel Application Form
x. Medicine Store Application Form
xi. Medicine Store Relocation Form
xii. Good Manufacturing Practice (GMP) Inspection Application Form
xiii. Application Form for Disposal of unfit Products
xiv. Application Form for Donation Importation
xv. Application Form for Advertisement Authorization
xvi. Application Form for Narcotic License
xvii. New Product Registration Application Form

xviii. Application Form for Medical Device Wholesaler
xix. Adverse Drug Reaction (ADR) Reporting Form
xx. Adverse Effects Following Immunization (AEFI) Reporting Form
xxi. Request for Access to Information Form 1
xxii. Request for Internal Review of a Decision Form 5

6.4. Registers:

i. Retained Premises Register
ii. Retained Personnel register
iii. Retained Products Register
iv. Clinical Trial Register

6.5. Reports:

i. Annual Financial Report
ii. Annual Performance Reports
iii. Survey Reports
iv. Annual Access to Information Implementation Report
v. Institutional Integrity Committee Reports

6.6. Names and Contacts of the Information Officers (Information Officers):

Name: Joseph Josiah
Mobile: +265 999 618 413 | +265 885 313 011
Email: jjosiah@pmra.mw

6.7. Contracts & Memoranda of Understanding (MoU):

i. Security Contracts
ii. Legal Service Contract
iii. Landscaping Contract
iv. Sanitation Contract
v. Telephone Service Contract
vi. Audit Service Contract
vii. Laboratory Contract
viii. Web Hosting and Bulk SMS
ix. Email Hosting Contract
x. Internet Service Provision Contract
xi. PMRA/MACRA MoU
xii. PMRA/KUHeS MoU

7.0. Information Management

Pharmacy and Medicines Regulatory Authority (PMRA) has established a comprehensive Registry dedicated to managing its records. Recognising the significance of accurate and accessible information, PMRA employs a systematic approach to document, classify, index, and store records efficiently. This includes both physical and electronic formats, ensuring the security, confidentiality, and integrity of the records. Through the utilisation of technologies, PMRA facilitates seamless record retrieval and tracking. The organisation also adheres to legal and regulatory requirements concerning record retention and disposal, ensuring compliance with relevant laws and guidelines. By maintaining this robust Registry, PMRA ensures that vital information is readily available for information seekers, supporting transparency, accountability, and informed decision-making within its regulatory processes.

8.0. Time Frame

The processing of the request for the information can be done within fifteen (15) working days, during which an information seeker is given a receipt of acknowledgement within five (5) working days. When information seeker is granted an access to information requested he/she is supposed to access that particular information within thirty (30) days. For more information on processes and procedures for accessing information refer to Access to Information Act (ATIA) or Information Guide by the MHRC.

9.0. Call for Citizens Participation

PMRA provides diverse channels: official website, social media platforms (Twitter, Facebook, LinkedIn), and Physical Correspondence for citizens to access information and report concerns.

10.0. Appendices

Appendix 1: FORM 1

REQUEST FOR ACCESS TO INFORMATION

PART A__PARTICULARS OF INFORMATION HOLDER

Name of the institution/ information holder……

Address of the institution/ information holder……..

Location
(District/Town/City/TA/Village……..

PART B __PARTICULARS OF INFORMATION SEEKER

Full
Name:……
……

Date of birth…….. Sex…..… National ID……
Number……
……
Postal
Address……
……
Physical
address……
Telephone
number……
……..
Email
address……

PART C__PARTICULARS OF PERSON ON WHOSE BEHALF THE REQUEST IS MADE (To be completed if request is being made on behalf of another person)

That indicates that you are authorized to act for the other person) Particulars of person on whose behalf the request is made (Please attach any documentation

Name: ……

Address: ……..

……

Identity Number: ……..

PART D__PARTICULARS OF INFORMATION BEING SOUGHT

Provide details about the nature of information being sought and justification.

Include relevant details that can help in retrieving the information, such as source, author, date of publication, etc.

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Explain the purpose for which you seek this information and why it is important that the Information should be provided to you.

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PART E__FORMAT OF INFORMATION BEING REQUESTED

State the format in which you want to access the information, e.g. print, electronic etc.

1. Normal print version (…..)
2. Braille print version (…..)
3. Other (state other preferred format)……..

Signed at……..this…….day of ……20 ……..

……

Signature of the information seeker

Appendix 2: FORM 5

REQUEST FOR INTERNAL REVIEW OF A DECISION

PART A__PARTICULARS OF INSTITUTION/INFORMATION HOLDER WHOSE DECISION IS A SUBJECT OF THIS REQUEST

Name of institution/information holder……

Address of the institution/information holder……..

Location (District/Town/City/)……

Email Address……

Telephone……..

PART B__PARTICULARS OF THE INFORMATION SEEKER

Full Name:……

Date of birth…… Sex…….. National ID Number……
Postal address……
……
Physical address……Telephone number……
Email address……

PART C__PARTICULARS OF PERSON ON WHOSE BEHALF THE REQUEST IS MADE

(To be completed if a request is submitted on behalf of another person)

Particulars of person on whose behalf the request is made

Full Name:……
……

Date of birth…… Sex…….. National ID Number…… Postal address……
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Physical address……Telephone number……
Email address……
Reason(s) for representing the information seeker……
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PART D__SUMMARY OF REQUEST

(Provided to you. Give reasons why you disagree with the decision of the information officer) provide a summary of your request for information and why the information should be

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PART E__TYPE OF ASSISTANCE REQUESTED

Whom the request for information was addressed) (Describe the type of assistance that you are looking for from the Head of the Institution to

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……..

Signed at ……..this…. day of ……. 20 …...

……..

Signature of the information seeker

Attach copies of the following documents if available__

1. The request for information Form
2. The information officer's response to the request for access to information