

MALAWI GOVERNMENT



MINISTRY OF HEALTH

NATIONAL MEDICINES POLICY

"Promoting Equity and Quality Pharmaceutical Services for a Healthier Nation"

Ministry of Health

P O Box 30377

Lilongwe, Malawi

June, 2015

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National Medicines Policy: Promoting Equity and Quality Pharmaceutical Services for a Healthier Nation

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ABBREVIATIONS AND ACRONYMS

ACT	Artemisinin Combination Therapy
AMRH	African Medicines Registration Harmonization
AU	African Union
c GMP	current code of Good Manufacturing Practices
CHAM	Christian Health Association of Malawi
CMS	Central Medical Stores
CMST	Central Medical Stores Trust
EHP	Essential Health Package
EML	Essential Medicines List
GoM	Government of Malawi
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
HMIS	Health Management Information Services
INN	International Non-Proprietary Name
ISO	International Standards Organization
MBS	Malawi Bureau of Standards
MDGs	Millennium Development Goals
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
NGOs	Non-Governmental Organizations
NMP	National Medicines Policy
NQCL	National Quality Control Laboratory
PMP	Pharmacy Medicines and Poisons
PMPA	Pharmaceutical Manufacturing Plan for Africa
PMPB	Pharmacy, Medicines and Poisons Board
PPP	Public-Private Partnership
QC	Quality Control
SADC	Southern Africa Development Cooperation
SRA	Stringent Regulatory Authorities
STG	Standard Treatment Guidelines
SWAp	Sector Wide Approach
TB	Tuberculosis
TRIPS	Trade Related Intellectual Property Rights
UNDP	United Nations Development Program
WHO	World Health Organization

FOREWORD

The development of the revised National Medicines Policy (NHP) has come at the right time when continuous provision of appropriate medicines of assured quality, in adequate quantities, and at reasonable prices is a concern for all national governments. Malawi too recognizes the need for the National Medicines Policy that is based on universal principles and equity, but adapted to the national situation to meet the needs of its population.

A good policy should be able to address the issues of timely access to adequate medicines and by those in need; medicines meeting appropriate standards of quality, safety and efficacy; quality use of medicines, and existence of vibrant medicines industry. I am pleased to note that the policy document has addressed these issues. However, I am aware of the many challenges the country is facing including low drug budgets with approximately ninety per cent of the budget being supported by our co-operating partners; drug pilferages; weak supply chain management systems exacerbated by poor quantification and specifications of medicines; increased demand for quality health by the populace, and the fragility of the country's pharmaceutical industry.

I am aware that the policy has been developed in a collaborative fashion through careful planning, consideration of emerging global pharmaceutical developments, the political dynamics and the involvement of all stakeholders besides the Ministry of Health, including regulatory bodies, professional organizations, health care professionals, academics, civil society, health planners and managers, co-operating partners and major Non-Governmental Organizations. The collaborative manner in the development of the revised NMP is a demonstration of the Government of Malawi's commitment to ensuring that Malawians enjoy the highest possible level of health which improves their quality of life.

It is my sincere hope that this policy document will henceforth become the single most important point of reference for identifying strategies and effective interventions needed to address myriad of pharmaceutical problems and provides a comprehensive framework to develop all components of a national pharmaceutical sector. I wish to reaffirm my Government's continued desire and commitment to making available adequate resources for procuring quality medicines and of the right quantities. As Minister of Health, I also wish to acknowledge, with gratitude, the continued and unwavering support the Government of Malawi is receiving from our co-operating partners. Finally, let me stress that having a policy in place is one thing, but ensuring that the policy achieves the intended objectives when fully implemented, is yet another. It is therefore my hope that the revised policy will go a long way in ensuring Malawians access medicines of good quality.



Hon. Dr. Jean A. N. Kalilani,
MP Minister of Health
Lilongwe, Malawi

15 June, 2015

PREFACE

The revised National Medicines Policy is the product of a concerted effort and support through intensive consultations involving individuals and various stakeholders including Government Ministries and Departments, Co-operating Partners and the Civil Society. The Ministry of Health would like to thank all of them, individually as well as the organizations they represented.

Special acknowledgement goes to the United States Agency for International Development (USAID) through the Support for Service Delivery Integration Program (SDDI-Systems project) for providing the financial and technical support towards the revised National Medicines Policy.

It is the hope of the Ministry of Health that the policy will be a roadmap for improving pharmaceutical services, including medicines, in Malawi in a unified and coordinated manner that will subsequently contribute to the improvement of health outcomes of Malawians.



Macphail Magwira, PhD
Secretary for Health
Lilongwe, Malawi

15 June, 2015

I.0 INTRODUCTION

As the Malawi population increases and the burden of disease changes with social and economic changes, a multitude of challenges face the health sector. These challenges include the HIV/AIDS pandemic and associated chronic pharmaceutical needs; limited financial and human resources coupled with a need for improved management of limited available resources; the increasing pharmaceutical needs covered under the Essential Health Package; active international trade agreements such as Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the challenges in achieving the Millennium Development Goals (MDGs). In dealing with these challenges, the Government of Malawi, through the Ministry of Health, recognized the need to review the National Medicines Policy; firstly as a commitment and guide for action, and secondary, to include emerging global pharmaceutical issues. In this Policy document, the words “medicines and medical products” have been used as advocated for by the World Health Organization.

Malawi developed the first National Medicines Policy (NMP) in 1991 in order to provide a well-defined framework for future pharmaceutical development in the country and to lay the foundation for ensuring equitable access to essential medicines. The Ministry of Health (MoH) has developed several documents to operationalize the policy, including the Pharmaceutical Services Strategic Plan, Standard Treatment Guidelines, and Essential Medicines List. In 2009 the Ministry developed the second, more comprehensive draft National Medicines Policy which articulates the country’s direction on medicines, including local production of medicines, quality assurance, and rational use of medicines. Since 2009, there have been marked changes in the health sector. New policy initiatives have emerged including, but not limited to, the new ACT regimen for malaria, the new HIV/AIDS Policy (2012-2017), the Malawi Health Sector Strategic Plan (2011-2016) and the Central Medical Stores (CMS) became a Trust in 2010.

Malawi, however, continues to suffer from shortages of essential medicines, which stifles the country’s ability to effectively deliver the Essential Health Package (EHP) whereby, the EHP is the basic health services considered to be necessary to maintain good health. While the overall availability of diagnostics and other medical supplies has recently improved, the shortage of essential medicines continues to be felt nearly in all health facilities. Factors that have been identified to contribute to the shortage are: lengthy procurements processes, poor quantification and specifications, and a weak logistical information system. The Ministry of Health is committed to reforms of the health sector including serious efforts to make medicines and other health care services available in both public and private sectors. It is within this context that the Ministry of Health has revised the National Medicines Policy.

2.0 SITUATIONAL ANALYSIS

The Malawi Health Sector Strategic Plan (2011-2016) identifies procurement, storage and distribution of medicines and medical supplies as critical. It also expresses the need to improve on inventory management, human resource capacity, accountability and transparency processes. Currently, pharmaceutical and allied staffs continue to be in short supply and there are still issues with shortages and stock-out of essential medicines at the facility level. Although procurement, storage and distribution have been centralized by making a Central Medical Stores (CMS) a Trust, parallel systems exist for medicines procurement, storage and distribution. Infrastructure for storage of medicines and supplies continue to be a concern at the districts and facilities at all levels of the healthcare system. Currently prescribing and dispensing roles among health professionals is unclear. With regulatory issues concerning program medicines and supplies procured under disease control programs, waivers for products already prequalified under the WHO Prequalification project as well as those registered by other regional and internationally acknowledged stringent national medicines regulatory authorities are not captured in policy or regulation. Roles of key stakeholders in the pharmaceutical sector are not clearly defined making the framework for policy implementation, monitoring and evaluation a challenge. Other challenges identified include:

- Increasing overall medicine expenditure.
- Fragmented structure of the public medicine supply system.
- Inadequate financial resources allocated to medicines.
- Inadequate Health Management Information System (HMIS).
- Irrational use of medicines in the public and private health care sectors.
- Increasing demand for health services and as a consequence, increasing demand for pharmaceuticals.
- Inadequate review process for existing medicine legislation coupled with unclear processes to carry this out.
- The failure of public and private medicine supply system to complement one another adequately due to lack of agreed modalities and memoranda of understanding.
- Inadequate monitoring mechanism for the policy implementation.
- Weak quality assurance and quality control system.

In dealing with the above challenges, the MoH mandated with providing overall policy direction for the delivery of health services in Malawi, has come up with the National Health Policy, which has informed the revision of the NMP. Additionally, medicine laws and regulations shall be updated to support the implementation of NMP. The National Essential Medicines List (NEML) and Standard Treatment Guidelines (STG) will be regularly updated. The NMP will serve as a framework for future pharmaceutical developments for both, the public and private health sector. The Government of Malawi is committed to achieving the overall goal and objectives of the NMP.

3.0 VISION OF THE NATIONAL MEDICINES POLICY

The National Medicines Policy envisions a Malawi with high quality pharmaceutical care and services.

4.0 MISSION AND GOAL OF THE NATIONAL MEDICINES POLICY

- 4.1** The National Medicines Policy provides a strategic framework through which provision of equitable access and rational use of good quality, safe, efficacious medicines and supplies at affordable cost shall be offered to the people of Malawi through well trained, motivated and dedicated personnel.
- 4.2** The overall goal of the Policy is to improve and sustain the health of the population of Malawi by ensuring the availability, rational use and access to safe, effective, good quality and affordable medicines and medical supplies.

5.0 OBJECTIVES OF THE NATIONAL MEDICINES POLICY

The objectives of the Policy are to:

- Promote the rational use of medicines by prescribers, dispensers and consumers;
- Strengthen quality assurance by ensuring that only quality, safe and effective medicines and medical supplies are sold or supplied to consumers by both the public and private sector;
- Establish financing mechanisms which ensure access to essential medicines;
- Improve the system of supply and management of medicines and supplies by rationalizing the procurement system and improving the drug distribution and management systems at all levels of health care delivery;
- Increase the quantity and quality of human resources for health involved in pharmaceuticals at all levels of the health sector;
- Promulgate the necessary legislation to support the implementation of the National Medicines Policy; and
- Provide a framework within which pharmaceutical services and products will be managed to promote good governance.

6.0 GUIDING PRINCIPLES

The guiding principles for National Medicines Policy are inspired by the Malawi Health Policy. These principles are:

- i. **Human Rights Based Approach and Equity:** All the people of Malawi shall have access to health services without distinction of ethnicity, gender, disability, religion, political belief, economic, social condition or geographical location. The rights of health care users and their families, providers, and support staff shall be respected and protected.
- ii. **Gender Sensitivity:** Gender issues shall be mainstreamed in the planning and implementation of all health programs, including pharmaceutical services.
- iii. **Ethical Considerations:** The ethical requirement of confidentiality, safety and efficacy in both the provision of health care and health care research shall be adhered to.
- iv. **Efficiency:** All stakeholders shall use available health care resources efficiently to maximize health gains.
- v. **Accountability:** All stakeholders shall discharge their respective mandates in a manner that takes full responsibility for the decisions they make in the course of providing health care.
- vi. **Community Participation:** Community participation shall be encouraged in the planning, management and delivery of health services.
- vii. **Evidence-based decision making:** Interventions shall be based on proven and cost-effective national and international best practices.
- viii. **Partnership and multisectoral Collaboration:** Public-Private Partnership (PPP) and multisectoral collaboration shall be encouraged and strengthened to address the determinants of health.
- ix. **Decentralization:** Health services management and provision shall be in line with the Local Government Act of 1998 which entails devolving health service delivery to District and City Councils.
- x. **Appropriate Technology:** All health care providers shall use health care technologies that are of assured quality, safety, efficacy and cost-effectiveness.

7.0 ELEMENTS OF THE NATIONAL MEDICINES POLICY

7.1 Management Framework for Policy Implementation

7.1.1 Preamble/Key Issues

It is established that every sector of health services provision, from prevention, diagnosis, prescribing, to clinical care and rehabilitation uses medicines or health commodity of one type or the other. In making all these products available for use in healthcare, they must be quantified, sourced or prepared, procured, stored, distributed, utilized, regulated and reported on by the Department of Health Technical Support Services which is responsible for the Pharmaceutical Services in the Ministry of Health. Additionally, all disease control programs that are handling medicines and health commodities need to be well coordinated at the central level. Notwithstanding, the pharmaceutical management structure at the central level is not that visible to be able to effectively and efficiently coordinate the implementation of the National Medicines Policy. The low visibility at the central level is exacerbated by the weak structure of the Pharmaceutical Services Unit under the Department of Health Technical Support Services (HTSS). To ensure the successful implementation of the NMP, all implementing partners will be required to develop strategic plans, detailing objectives, timelines and assigning of responsibilities.

7.1.2 Objectives

- Strengthen Pharmaceutical Services Management Administration to enable it to play its expected role in the administration of pharmaceutical services in Malawi.
- Ensure effective implementation, monitoring and evaluation of the National Medicines Policy.

7.1.3 Policy Statements

- 7.1.3.1 The Ministry of Health will create a Department of Pharmaceutical Services in the Ministry of Health.
- 7.1.3.2 The Directorate in the Ministry of Health responsible for Pharmaceutical Services shall establish appropriate mechanisms for the implementation, monitoring and evaluation of the policy.
- 7.1.3.3 The Ministry shall develop appropriate guidelines to address gender disparity issues in the pharmaceutical sector in Malawi.
- 7.1.3.4 All implementing partners will be required to draw up a 3-year strategic plan, detailing strategies and timelines for the achievement of the NMP objectives and submit to the Ministry of Health Directorate responsible for Pharmaceutical Services.

7.2 Human Resource Capacity Development

7.2.1 Preamble/Key Issues

Since 1991, facilities and pharmaceutical services expansion has not matched with the numbers, diversity and capacity of pharmaceutical services personnel. Although the College of Medicine has started training of pharmacists locally, it is constrained by inadequacy of training, research, human and infrastructural capacity. There is unclear service conditions and career progression in the public sector coupled with the lack of an effective retention strategy. Currently, there are limited continuing professional education and postgraduate training programs. In addition, training for auxiliary pharmaceutical providers has not been formalized and structured. Available pharmaceutical service staffs are unevenly distributed while the involvement of the private sector and partners in human resource training and development is low.

7.2.2 Objective

- Embark on human resource development programs that will ensure that adequate, appropriately trained and well-motivated pharmaceutical personnel are available in the health sector to provide effective and efficient services.

7.2.3 Policy Statements

- 7.2.3.1 The Ministry of Health shall increase student enrollment into the Pharmacy Department of the College of Medicine under government sponsorship.
- 7.2.3.2 Government of Malawi shall support further training of teaching and research staff and improve training and research infrastructure.
- 7.2.3.3 Appropriate client-oriented continuing professional education and postgraduate training programs in collaboration with other statutory organizations and professional bodies, shall be instituted to improve performance of both public and private health sector.
- 7.2.3.4 The Ministry of Health shall define and develop a clear scheme of service for pharmacists and other programs that aim at providing clear career prospects and opportunities for attracting and maintaining qualified personnel.
- 7.2.3.5 Formal and structured training for auxiliary pharmaceutical providers especially those at the lower level healthcare facilities of the pharmaceutical delivery system will be actively pursued.
- 7.2.3.6 The Ministry of Health shall provide pharmaceutical personnel in all facilities according to recommended staff establishments.

- 7.2.3.7 Private sector and partners' involvement in human resource training and development shall be encouraged and promoted to leverage on numbers and financial resources.

7.3 Legislation and Regulation

7.3.1 Preamble/Key Issues

Amendment of Pharmacy, Medicines and Poisons Act (PMP Act) has taken quite a long time to achieve. In doing so, it will be pertinent to consider a change of name of the Board to Pharmacy, Medicines and Health Products Regulatory Authority (PMHRA). Currently, the scope of products that are regulated by Pharmacy, Medicines and Poisons Board (PMPB) established under the PMP Act do not include other healthcare products and commodities such as condoms, syringes and needles, surgical gloves and bed nets. There is need, therefore, to expand the scope of products to be regulated and hence the need to also review the name of the regulatory body to the proposed PMHRA. The amendments must also deal with the weak sanctions and penalties in the current Act. There is need for legal backing for the workings of the National Quality Control Laboratory and the Pharmacovigilance program of the PMPB and the management of narcotics, psychotropic substances and precursors in both public and private sector. At present, there are inadequate regulations and guidelines to fully support the implementation of the Act.

7.3.2 Objectives

- Ensure that existing medicines legislation is strengthened/reviewed/amended and enforced.
- Ensure appropriate regulations and guidelines are promulgated to facilitate enforcement and compliance to existing laws on medicines.

7.3.3 Policy Statements

- 7.3.3.1 The Ministry of Health shall actively participate in the amendment process of the PMP Act to ensure it is completed.
- 7.3.3.2 The Ministry of Health shall make penalties and sanctions stiffer in the new law to serve as deterrent.
- 7.3.3.3 The scope of products to be regulated under the PMP Act shall be expanded to include other healthcare products and commodities (including condoms, syringes and needles, surgical gloves, bed nets, etc.) in line with international best practice.
- 7.3.3.4 Provision shall be made in the law to give legal backing to:

- 7.3.3.4.1 The working of the National Quality Control Laboratory and the pharmacovigilance program of the PMPB.
- 7.3.3.4.2 Management of narcotics, psychotropic substances and precursors in both public and private sector.
- 7.3.3.5 Regulations and guidelines shall be developed and enforced by the PMPB in the areas of Import and Export control, drug donations, inspection and licensing of medicines manufacturing, warehouse, and storage facilities in both public and private sectors.
- 7.3.3.6 The following general regulatory policies shall apply:
 - 7.3.3.6.1 Government of Malawi, quasi-government and private not-for-profit facilities shall not be permitted to accept medicines that are near expiry, expired or are not needed at that level of healthcare.
 - 7.3.3.6.2 All medicines to be used in Malawi for the health sector shall be duly registered with the national regulatory authority - currently the PMPB.
 - 7.3.3.6.3 The PMPB shall be duly notified of any variation in respect of source, documentation, packaging and indications for existing medicines and these will be duly registered.
 - 7.3.3.6.4 Medicines imported for specific use of individual patients shall be exempted from registration requirements. Such requests will be certified by a local medical specialist in the related field and an import permit obtained from the PMPB.
- 7.3.3.7 Donated medicines will be exempted from registration requirements; however, the donations will be required to conform to the National Guidelines on drug donations.
- 7.3.3.8 The PMPB will ensure that there are functional national pharmacovigilance and quality assurance systems for the safety of the public and provision of timely information on medicines.
- 7.3.3.9 The PMPB will compile a register of medicines, which will include a cross-index of generic and brand names for all medicines on the market every 3 years with an annual update. Medicines in the register will be classified as Prescription Only Medicines (POM), Pharmacist Recommended Medicines (P) and Over the Counter Medicines (OTC).

7.4 Financing of Medicines

7.4.1 Preamble/Key Issues

Notwithstanding the Decentralization Act, the drug budget of Government of Malawi remains over centralized. The possibility of decentralizing this for efficiency and avoidance of stock-outs should be explored. Drug financing is mainly by the donor community. For example, most of

the medicines for Malaria, HIV/AIDs and TB are provided by donors through the Global Fund and other international organizations such as UNICEF although GoM continues to finance medicines for complicated malaria. Facilities that procure medicines from Central Medical Stores Trust (CMST) at 12.5% handling charges consider the overall cost higher than buying from elsewhere. Ordering is done based on quantities without cost and no feedback is received so consumption in terms of cost is not known by the facility. Most District Health Offices have huge debts with CMST because of inadequate drug budgets. Prices of medicines are high because of the Value Added Tax (VAT) imposed on raw materials of the local manufacturing industry by the Malawi Revenue Authority. Additionally, prices of most essential medicines vary considerably from one supplier to another. Christian Health Association of Malawi (CHAM) facilities procure from both the private wholesalers and CMST so they do not experience stock-outs and shortages often. CHAM provide cost recovery services to clients as opposed to free supplies to clients at the point of service delivery in the public health facilities. Procurement is on cash and carry basis from CMST while the private sector gives credit.

7.4.2 Objective

- Institute a reliable and sustainable drug financing mechanism that ensures unhindered access to quality, safe, efficacious and affordable medicines to the populace.

7.4.3 Policy Statements

- 7.4.3.1 The Ministry of Health shall collaborate with the private sector and donor agencies in the funding of drug supplies to the public sector.
- 7.4.3.2 The Ministry of Health shall timely pay suppliers for the regular supply of needed medicines, medical devices and consumables.
- 7.4.3.3 The CMST shall prioritize value for money for the medicines that are procured as prescribed in the Procurement Act of 2003.
- 7.4.3.4 The Ministry of Health shall periodically review and standardize mark-ups for medicines.
- 7.4.3.5 The Ministry of health shall provide free of charge to patients medicines provided through donations or funded by the Global Fund.
- 7.4.3.6 The Ministry of Health shall provide to patients free of charge at the point of delivery medicines funded by the GoM. However, the Ministry of Health shall explore mechanisms for co-payment after undertaking thorough consultations with relevant stakeholders.
- 7.4.3.7 The Government of Malawi shall finance the procurement and management of adequate quantities of good quality essential medicines for the public sector.

- 7.4.3.8 Government of Malawi through the Ministry of Health and relevant regulatory agencies shall exempt selected essential medicines from Value Added Tax (VAT) and other forms of taxation. Such exempted medicines shall be reviewed every two years.
- 7.4.3.9 Raw materials used for local manufacturing of medicines shall be subject to VAT exemption on conditions to be determined by Parliament.
- 7.4.3.10 The Ministry of Health shall develop a national pricing policy to ensure that essential medicines are affordable.
- 7.4.3.11 The Ministry of Health shall explore various forms of health insurance schemes and establish the most viable scheme to facilitate access to medicines at service delivery points.

7.5 Medicines Selection and Needs Quantification

7.5.1 Preamble/Key Issues

Medicine selection for public sector use is based on the Essential Medicines List (EML) and national Standard Treatment Guidelines (STG). Needs quantification for the public sector should be based on returns received from the facilities and calculated based on past consumption records. Currently, quantification is usually manually done at the health facility level with a degree of automation at the central level. The EML is not updated and the national facility medicines and therapeutics committees are not functional. STG and EML copies are not readily available and/or not widely circulated. The use of registered medicines list at the PMPB is not indicated in the Policy.

7.5.2 Objectives

- Ensure that effective quantification for essential medicines for use in public health facilities is evidence-based to avoid stock outs.
- Ensure the selection of medicines for use at all levels of the health care delivery system is appropriate to meet health care needs of the population.

7.5.3 Policy Statements

- 7.5.3.1 The Ministry of Health shall strengthen supply-chain information management systems to collect and use facility consumption data to inform and update quantification decisions.

- 7.5.3.2 Quantification of medicines from all facilities shall be improved by progressively making it electronic.
- 7.5.3.3 The Ministry of Health shall promote use of the EML in the selection of pharmaceutical products before procurement, prescribing and dispensing in the public health sector.
- 7.5.3.4 The Ministry of Health shall encourage the selection, tendering, purchasing, prescribing and dispensing of interchangeable multi-source pharmaceutical products, using the International Non-Proprietary Name (INN) or generic name.
- 7.5.3.5 Membership of the National Medicines and Supplies Committee and their Terms of Reference shall be reviewed every two years to make the Committee more functional.
- 7.5.3.6 The quantity of medicines, vaccines, medical devices and consumables selected shall be based on health needs including special requirements for certain sectors and financial resources.

7.6 Procurement, Distribution and Storage of Medicines

7.6.1 Preamble/Key Issues

The CMST was established outside the Ministry of Health system to ensure efficiency in procurement, storage and distribution but has not yet functioned up to the expected standards. The health sector continues to experience stock-outs and shortages of medicines. The lead time for procurement of medicines by the CMST has been found to be too long possibly due to the time taken for supplier cGMP inspection by PMPB and/or the human resource capacity for both inspection and tender evaluation. Malaria medicines and other program medicines are procured and distributed through a parallel system. Central Medical Stores Trust procures and supplies all needs of the central and district hospitals, and health centres. However, many district hospitals are experiencing stock-outs since they receive, on the average, between 40-60% of their requisitions. They are also unable to fill in the gaps through procuring from the private sector because of inadequate drug budgets. The CMST is challenged by slow debt recovery process, limited warehousing and storage facilities and weak financial base.

The slow progress in implementation of CMST reforms is limiting its capacity to take over the Malaria, Family Planning, HIV, and health kit parallel supply chains. Inadequate store infrastructure constrains implementation of good storage practices at health facility level

7.6.2 Objectives

- Ensure that there is a streamlined and reliable procurement system for medicines and supplies to obtain the lowest possible price without compromising on quality, safety, efficacy and reliability of the process.

- Ensure adequacy of warehousing, storage and distribution infrastructure and systems throughout the healthcare system in Malawi.
- Ensure prompt, secure and efficient distribution of medicines and supplies to all levels of the healthcare system.

7.6.3 Policy Statements

- 7.6.3.1 Medicine specifications shall become unified and codified for purposes of efficient procurement, storage and distribution.
- 7.6.3.2 Public sector procurement shall be made by generic names and shall always accord priority to essential medicines to ensure that these are available in sufficient quantities to meet the needs of the population.
- 7.6.3.3 Procurement of essential medicines for the public health sector shall be undertaken by the Central Medical Stores Trust and shall be restricted to procuring only those medicines which are on the EML and are registered by the PMPB for use in Malawi.
- 7.6.3.4 Where a product for which a tender has been won is not registered by the PMPB, an abridged registration process shall be undertaken by the PMPB before the supply contract is awarded.
- 7.6.3.5 The CMST shall procure medicines from the private sector of health care provided that the supplier is licensed as a wholesaler by the PMPB.
- 7.6.3.6 The Ministry of Health shall put mechanisms that will ensure agencies, suppliers, donors and facilities using the services of the CMST enter into written contracts spelling out the obligations of each party.
- 7.6.3.7 The Ministry of Health shall create buffer stocks in district health facilities to replace emergency procurement.
- 7.6.3.8 Parallel systems for storage and distribution of medicines and supplies in the public sector shall be consolidated into the CMST system to improve capacity and efficiency.
- 7.6.3.9 The Ministry of Health shall support the improvement of the infrastructure and capacity, change of fleet and communication and ICT facilities at the CMST to facilitate efficient distribution.
- 7.6.3.10 The Ministry of Health shall put in place mechanisms for the exchange and or sale of medicines and supplies in case of unforeseen stock surplus between the public sector facilities.
- 7.6.3.11 Private sector procurement shall follow cost-effective market operations, but conform strictly to registration and quality control requirements.

- 7.6.3.12 The private sector medicine supply system shall operate and be governed by a revised and clear legislation and regulations specifying the professional standards required for operating the system.
- 7.6.3.13 The Ministry of Health shall promote equitable access and maintenance of product quality integrity throughout the distribution chain.

7.7 Medicines Donations

7.7.1 Preamble/Key Issues

Medicines, supplies and emergency kits are mainly donations and are received close to expiry dates. Donations are usually not based on needs or request from recipient facilities, sometimes resulting in overstocking and availability of un-needed medicines at different levels of healthcare services. There are multiple donations to health facilities, districts and local NGOs that are not coordinated through MoH headquarters. Although importation of donations is under control of PMPB, it is not fully inspected at points of entry resulting in donations that contain unregistered medicines, varying specifications and labeled in languages other than English. There is a huge burden of disposal of unusable and expired items as a result of unwanted and expired donated medicines and medical supplies.

7.7.2 Objective

- Ensure that medicines donations conform to required standards and are useful to the needs of Malawi health services.

7.7.3 Policy Statements

- 7.7.3.1 All donations of medicines and medical devices or supplies, no matter the source shall conform to the requirements of the Ministry of Health guidelines on drug donations.
- 7.7.3.2 No consignment of drug donations shall be allowed or accepted as donation if it is not labeled in English or a translation thereof.
- 7.7.3.3 The PMPB shall inspect and issue permits for importation of donations before they are cleared through Customs Department.

7.8 Local Production of Pharmaceuticals

7.8.1 Preamble/Key Issues

Local capacity for the production of pharmaceuticals is limited and mainly for basic generic products. There is limited infrastructural and human resource capacity and financial and other incentives to promote the sector. The quality assurance capacity and regulatory oversight to

ensure strict adherence to current codes of Good Manufacturing Practices (cGMP) is also limited.

7.8.2 Objective

- Promote the production, packaging and marketing of efficacious, safe and affordable essential medicines within Malawi.

7.8.3 Policy Statements

- 7.8.3.1 A list of registered local pharmaceutical products and manufacturers shall be compiled, published and reviewed by the PMPB annually in accordance with the provisions of the existing laws.
- 7.8.3.2 Only medicines conforming to nationally accepted and/or internationally recognized quality standards shall be permitted to be manufactured and distributed in the country.
- 7.8.3.3 The PMPB shall institute regular and thorough inspection procedures for manufacturing and quality control facilities.
- 7.8.3.4 The PMPB will put in place mechanisms for product recall procedures for pharmaceutical companies.
- 7.8.3.5 The PMPB shall enforce the withdrawal from circulation of medicinal products, which have been shown by testing or demonstrated otherwise to be of unacceptable quality.
- 7.8.3.6 The manufacture, exportation and distribution of counterfeit, substandard finished products and importation of substandard and expired raw materials shall not be permitted and shall be punishable by the provisions of the PMPB Act.
- 7.8.3.7 The Government of Malawi, through the Ministry of Health shall support the private sector through various industrial funds and foreign grants available to it to develop the pharmaceutical manufacturing sector in line with the African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA).
- 7.8.3.8 The Government of Malawi, through the Ministry of Health shall provide the needed financial and technical support to promote the development and growth of a competitive local pharmaceutical industry.
- 7.8.3.9 The procurement and use of locally manufactured pharmaceutical and medicinal products shall be encouraged.
- 7.8.3.10 Local manufacturing of medicines shall be supported and improved through organization of GMP training, with donor support where possible.

7.9 Quality Assurance and Quality Control

7.9.1 Preamble/Key Issues

The National Quality Control Laboratory (NQCL) under the PMPB lacks adequate infrastructure, equipment and human resource to prosecute its mandate successfully. Partners and donors do not have much confidence in the capacity of the laboratory for testing and approving medicines imported with donor support. Not much quality assurance interventions exist in the procurement and distribution system by the CMST, PMPB and its NQCL. Human resources for health capacity in NQCL and PMPB remain weak to ably execute their mandates.

7.9.2 Objective

- Establish a robust quality control infrastructure under the PMPB to assure quality of medicines and supplies throughout the supply chain in both the public and private health sector.

7.9.3 Policy Statements

- 7.9.3.1 The Ministry of Health shall put in place mechanism to facilitate collaboration between the Pharmaceutical Services Division of the Ministry of Health, PMPB, CMST and Malawi Bureau of Standards (MBS) to enforce standards.
- 7.9.3.2 The Government of Malawi, through the Ministry of Health shall secure support for the provision of minilabs as field test kits for qualitative test of medicines at each district and other healthcare facilities.
- 7.9.3.3 The infrastructure, equipment and human resource capacity of the existing PMPB including the NQCL shall be strengthened and prepared for ISO 17025 and WHO accreditation.
- 7.9.3.4 The Ministry of Health shall put in place systems for acceptance of quality assurance information from WHO Prequalification project and other stringent regional and international MRAs.
- 7.9.3.5 Quality Assurance principles shall be applied throughout the supply chain for medicines and supplies.

7.10 Rational Medicines Use

7.10.1 Preamble/Key Issues

National Essential Medicines List and Standard Treatment Guidelines have not been reviewed to take care of current trends and new treatment protocols issued by disease control programs and specialized types of medicines such as oncology products. Policy should support the elimination of mono therapies and phasing in of combination therapies for malaria for both

public and private sectors. Since the revised policy has included drug quantification based on consumption rate as a basis for good practice in procurement of medicines there will be need for proper reporting. Unfortunately, medicines and therapeutics committees at national, district and facility levels are non-functional. Prescriptions and dispensing of medicines is done at different levels by lower cadre of staff in the public health system and this is contributing to the irrational use and drug abuse. There is no streamlining of prescriptions and dispensing of medicines to avoid poly pharmacies. Again, there are no clear mechanisms to control advertisements of conventional as well as traditional medicines in both the print and electronic media. There are currently no restrictions on the advertisement and sale of herbal medicines in the country, and this is considered a major gap in the regulation of health services, as advertisements on traditional medicine and practitioners are quite common and quite often misleading.

7.10.2 Objective

- Institute policy measures to promote and facilitate the rational use of medicines by prescribers, dispensers and consumers in both the public and private health sector.

7.10.3 Policy Statements

- 7.10.3.1 Medicines and Therapeutics Committees shall be strengthened and made functional at the National, District and Facility levels of the healthcare delivery system.
- 7.10.3.2 The National Medicines and Therapeutic Committees shall be responsible for the development and periodic revision of the EML and the STGs.
- 7.10.3.3 The Essential Medicines List and Standard Treatment Guidelines shall be regularly updated, at most every two years because of advances made in medicine therapy. The updated list will be distributed to all registered medical professionals and health partners in the country.
- 7.10.3.4 Suggestions for amendments to the EML shall be made in writing to the Committee of EML, giving justification for each suggested amendment.
- 7.10.3.5 New medicines shall only be introduced into the EML if they offer distinct advantages over existing medicines on the EML and have favorable benefit/risk ratios.
- 7.10.3.6 Essential Medicines List shall indicate the level of use of each item, based on the classification to be specified by the Ministry of Health.
- 7.10.3.7 The PMPB shall be responsible for monitoring and ensuring ethical standards for drug advertisement and promotion in accordance with the PMP Act.
- 7.10.3.8 Public advertising materials on medicines, whether in the print or electronic media shall be vetted by the PMPB and the written approval of the Board shall be obtained before the material is used.

- 7.10.3.9 Drug promotional activities shall be in line with the National Medicines Policy objectives. In this respect, whenever the brand name of a drug is used in any form of promotional or educational material, the generic name of the drug will be given due prominence. In the case of printed materials, such as advertisements on billboards, posters and publications, the generic name will be prominent and positioned underneath the brand name.
- 7.10.3.10 Promotion and advertisements of Prescription-only Medicines (POM) and Pharmacist recommended medicine (P) shall be restricted to health professional publications only.
- 7.10.3.11 Promotion and advertising of medicines shall not be permitted at public places including lorry parks and markets and in all modes of transportation except with written approval from PMPB under the PMP Act.
- 7.10.3.12 No advertisement shall be permitted for medicines and herbal medicines for disease conditions that shall be specified by the Ministry of Health.
- 7.10.3.13 Dispensing of medicines shall be done only upon the presentation of prescription from certified medical personnel.

7.11 Traditional and Alternative Medicines

7.11.1 Preamble/Key Issues

Although widely believed to be effective and potentially accessible to many Malawians, documentation of the constituent herbs as well as the active ingredients of local herbal medicines remain poor. There are currently no laws or regulatory control on traditional, herbal or homeopathic (complimentary) medicines despite being used widely by Malawians. The country is also witnessing unprecedented influx of homeopathic medicines from other countries.

7.11.2 Objective

- Promote the proper production, distribution, marketing and use of Traditional (complimentary) Medicines in Malawi.

7.11.3 Policy Statements

- 7.11.3.1 The Ministry of Health shall promote and encourage research, development and rational use of herbal medicines that are widely believed to be efficacious, safe and of good quality.
- 7.11.3.2 The Ministry of Health shall be responsible for supervising training and register herbal practitioners operating in Malawi and regulate, through the PMPB or such

other Board as the Ministry may establish their activities to ensure that they conform to the set standards.

- 7.11.3.3 All traditional medicine products shall be subjected to the regulations and standards provided for under the PMPB Act.
- 7.11.3.4 The Government of Malawi, through the Ministry of Health shall encourage and support financially, where necessary, research institutions, including the country's universities in identifying the useful components of herbal medicines for treatment of endemic diseases, their formulation into standardized products of reliable quality, and rationalization of their use.
- 7.11.3.5 The Government of Malawi, through the Ministry of Health shall promote the exchange of research findings with other countries and international agencies such as the WHO, UNDP, and shall encourage and support the participation of local drug research institutions in international drug research activities.
- 7.11.3.6 The Government of Malawi, through the Ministry of Health shall encourage the cultivation and sustainable harvesting of medicinal plants in collaboration with the Ministry of Agriculture and Food Security, Ministry of Lands, Forestry and Mines and any other related key sectors.
- 7.11.3.7 The Ministry of Health shall maximize the benefits and minimize the hazards associated with the use of Traditional (complimentary) Medicines by supporting the development and implementation of the Traditional Medicines Policy in liaison with Traditional Healers or Herbalists Association of Malawi.

7.12 Good Governance for Medicines

7.12.1 Preamble/Key Issues

Issues of good governance for medicines were not well articulated in the previous National Medicines Policy. Drug management services and record keeping system at the user level is still manual and susceptible to abuse. Pilfering of medicines and other health commodities is still a problem in the supply chain and user facilities. Application of sanctions in cases of corruption, pilfering and drug leakages is weak and highly centralized. There is need to decentralize to lower levels application of sanctions so that corrective measures are taken at the facility or district level.

7.12.2 Objectives

- Put in place a decentralized and computerized supply chain management and good record keeping system to curb susceptible abuse.
- Put measures in place to curb corruption, drug pilferages and leakages in the pharmaceutical sector, through the application of transparent and accountable administrative procedures and the promotion of ethical practices among health professionals.

7.12.3 Policy Statements

- 7.12.3.1 The Ministry of Health shall put in place programs for all stakeholders on the potential for corruption in the pharmaceutical sector and its impact on health systems functioning.
- 7.12.3.2 The Ministry of Health shall put in place systems to increase transparency and accountability in medicines regulatory processes and supply management.
- 7.12.3.3 The Ministry of Health shall seek partnership with development partners, NGOs, and the private sector to computerize supply chain information, management and reporting of medicines systems in all health facilities, including the end user.
- 7.12.3.4 Ministry of Health shall put in place mechanisms to reward those that comply to the rules and sanctions for non-compliance.
- 7.12.3.5 Legislation shall be enacted to provide stiffer sanctions for theft of medicines and medical supplies and that the mandate to exercise disciplinary action will be decentralized to lower levels of the healthcare system.

7.13 Public Private Partnership and Inter-sectoral Collaboration

7.13.1 Preamble/Key Issues

The private sector and donor funded interventions play a major and important role in the pharmaceuticals sector in Malawi. CHAM and other NGOs have in place robust medicines management systems that impact greatly on healthcare in Malawi. However, collaboration remains weak and information flow between Ministry of Health and health partners, training institutions, regulatory bodies, CHAM and the private sector is informal, nonfunctional and not well structured.

7.13.2 Objective

- Formalize and strengthen the role of health partners, training institutions, regulatory bodies, CHAM and the private sector in the provision of pharmaceutical services in Malawi.

7.13.3 Policy Statements

- 7.13.3.1 The Ministry of Health shall formalize collaborations with the private sector, donor health partners and NGOs through public-private partnerships to ensure efficiency of the country's system.

- 7.13.3.2 The Government of Malawi, through the Ministry of Health shall work with the private sector to leverage on their capacity, expertise and investment for purposes of increasing access to affordable, quality pharmaceutical services.
- 7.13.3.3 The private sector involvement will conform to existing laws regulating PPPs in Malawi.
- 7.13.3.4 Private sector facilities shall participate fully in product quality surveillance and pharmacovigilance programs at all levels of the healthcare system.

7.14 Emerging Diseases and Pharmaceuticals

7.14.1 Preamble/Key Issues

New diseases may emerge at any time in the world, while existing diseases may pose new challenges at one time or the other. Such diseases usually become issues of concern when treatment is very expensive and out of the reach of most of the people, or the treatment or control is simply difficult or not available at all. Unfortunately, Malawi is experiencing the re-emergence of Non-Communicable Diseases (NCDs) and Tropical Neglected Diseases.

7.14.2 Objective

- Provide needed medicines to adequately treat and control such diseases, and also make other resources adequately available where there are special needs.

7.14.3 Policy Statements

- 7.14.3.1 Ministry of Health shall provide needed medicines for new diseases and existing ones posing new challenges. Both the public and private sectors will be involved.
- 7.14.3.2 The Ministry of Health shall collaborate with the relevant international bodies to mobilize adequate resources for these cases, where they cannot be provided by the country alone.
- 7.14.3.3 Where emerging diseases with no previously known treatment have been identified, the Government through the Ministry of Health shall support and fund the research, development and local manufacture of the needed medicines and herbal preparations.

7.15 Research and Development

7.15.1 Preamble/Key Issues

No baseline study of drug utilization pattern exists. Operational research on drug consumption patterns is not formally undertaken. The abundance of medicinal plants in Malawi requires a well-coordinated and intensified research program to identify, classify and document their uses and potency in the management of disease conditions in the country.

7.15.2 Objective

- Identify and support scientific and operational research and development activities in the pharmaceutical sector and in traditional medicines.

7.15.3 Policy Statements

- 7.15.3.1 Research institutions shall be strengthened and supported to ensure the achievements of the objectives of the pharmaceutical sector.
- 7.15.3.2 The Ministry of Health, through tertiary institutions and other research centres shall support collaboration between local drug manufacturers and herbal industries.
- 7.15.3.3 Research priorities shall be determined on the basis of major health problems encountered in the country.
- 7.15.3.4 Research shall be aimed at supporting essential medicines program and rational use of medicines.
- 7.15.3.5 The Government of Malawi, through the Ministry of Health shall support areas of health research that have bearing on the National Medicines Policy.
- 7.15.3.6 The Ministry of Health shall encourage the development of high level multidisciplinary research in disciplines such as medicine, pharmacy, pharmacology, medicinal chemistry and the training of research personnel into the relevant areas of interest.
- 7.15.3.7 The Ministry of Health shall make use of research findings in making necessary adjustments in its strategies to ensure achievement of the objectives of the National Medicines Policy.
- 7.15.3.8 Clinical trials involving pharmaceutical products shall be carried out in accordance with international guidelines and national regulations.
- 7.15.3.9 The Government of Malawi through the Ministry of Health shall support research studies in the field of pharmaceutical products and services.

7.16 Intellectual Property Rights (TRIPS)

7.16.1 Preamble/Key Issues

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the most relevant of all the various agreements of the World Trade Organization (WTO) for the health sector. The TRIPS agreement introduces global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including pharmaceutical products and processes. The TRIPS agreement raises concerns about the major impact of this agreement on

people's access to medicines and public health. In order to access the flexibilities, governments, especially developing countries are required to bring their legislation on intellectual property rights to conform to the TRIPS agreement. Patent protection has been an incentive for promoting research and development of new medicines. However, its implementation should not constitute a hindrance to access to essential medicines. Malawi has weak legal framework in enforcing intellectual property rights especially in the area of pharmaceutical products and processes.

7.16.2 Objective

- Ensure that legislation and regulations developed maintain a balance between the minimum standard of intellectual Property Rights protection and the public health good.

7.16.3 Policy Statements

- 7.16.3.1 In implementing regulations related to intellectual property rights, the Government of Malawi, through the Ministry of Health shall take advantage of all the safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals.
- 7.16.3.2 The Government of Malawi through the Ministry of Health shall not enact legislation and regulations more stringent than the TRIPS requirement.
- 7.16.3.3 The Government of Malawi through the Ministry of Health shall put in place mechanism to ensure that public health interests are protected when trade matters conflict with health of Malawians.
- 7.16.3.4 The Ministry of Health shall actively collaborate with the Ministry of Industry and Trade and Ministry of Justice and other relevant agencies in the area of intellectual property rights in developing consistent legal framework that enhances access to essential medicines.
- 7.16.3.5 Parallel importation shall be permitted for pharmaceuticals when the protection of the health of the public is concerned.
- 7.16.3.6 The Ministry of Health shall explore existing mechanisms provided by international agreements to protect public health, especially those that affect access to affordable, good quality and essential medicines.
- 7.16.3.7 The Government of Malawi through the Ministry of Health and other relevant agencies shall grant compulsory licensing (e.g. local manufacture and generic version of patented products) to promote competition and access to medicines when the health of the public is at stake.
- 7.16.3.8 Regarding the exploitation of the rights conferred by patency on pharmaceuticals, the Government of Malawi through the Ministry of Health and other relevant

agencies shall design laws that prescribe a limited period immediately preceding the expiry of the patent for its agency or a third party to conduct tests on the product required for regulatory approval in the country.

- 7.16.3.9 The Government of Malawi through the Ministry of Health shall exercise flexibility of early working and allow a third party to manufacture and store the product, so that when the patent expires, a generic product can enter the market immediately.

7.17 Regulatory Harmonization

7.17.1 Preamble/Key Issues

In order to harmonize requirements for the regulation of medicines worldwide, a number of initiatives are taking place in various regions of the world. Among them are the African Medicines Registration Harmonization project and the SADC harmonization initiatives. Aside these, the WHO prequalification project (WHO PQP), which undertakes to prequalify products and manufacturing facilities as well as quality control laboratories and contract research organizations, also exist. In the recent past there have been controversies over the acceptance of products and facilities pre-qualified by the WHO PQP and other Stringent Regulatory Authorities (SRAs).

7.17.2 Objective

- Provide for recognition by and the participation of Malawi in regional, international and other medicines policy and regulatory harmonization initiatives.

7.17.3 Policy Statements

- 7.17.3.1 The Ministry of Health through the PMPB shall undertake joint inspections and evaluation programs at SADC and recognize reports of the same.
- 7.17.3.2 The Ministry of Health shall put in place systems to accord recognition for products and facilities that are pre-qualified under WHO PQP, SADC or AMRH project.
- 7.17.3.3 The Government of Malawi shall take into consideration the AU Model laws and regulations in the development, review and amendments of medicines law and regulations in Malawi.
- 7.17.3.4 Where no specific guidelines, forms or definitions are available under the PMPB Act, the Government of Malawi through the Ministry of Health shall adopt and implement guidelines, forms and definitions promulgated by the SADC.

8.0 MONITORING AND EVALUATION OF THE POLICY

The National Medicines Policy will be monitored using a comprehensive monitoring and evaluation framework based on the indicators that will be included in the health sector monitoring and evaluation matrix. There will also be a mid-term evaluation of the policy to assess whether implementation is on course or not.

9.0 REVOCATION AND REVIEW OF THE POLICY

The 2009 National Drugs Policy is hereby revoked and replaced with this policy which will be reviewed every five years.