

# NATIONAL MEDICINES POLICY

### **JULY 2015**



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#### Published by the Ministry of Health, Uganda

#### First Edition: July 2015 © 2015 Ministry of Health, Uganda

#### Printed and bound in Uganda

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## NMP TASK TEAM

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### FOREWORD

The development of this National Medicines Policy (NMP) 2015 has been informed by the second National Health Policy (NHP) 2010, the Health Sector Development Plan (HSDP) 2015–2020, the current state of the pharmaceutical sector and global health discourse particularly the post-2015 sustainable development agenda.

The NMP 2015 was developed through a highly consultative process involving Ministry of Health (MoH), other Government ministries, regulatory agencies, academia, professional associations, Health Development Partners (HDP), district health departments, central medicineswarehouses, private-not-for-profit sector (PNFP), private sector, and civil society.

The goal of the NMP 2015 is the progressive realisation of the highest attainable standard of health by Ugandans, by ensuring access to, and appropriate use of good quality, affordable essential medicines and health supplies. The NMP underscores three important principles of quality of care, equity and efficient utilisation of available resources. The NMP shall focus on supporting the achievement of Universal Health Coverage; increasing funding for medicines; strengthening partnerships and collaboration for health; and on increasing the capacity of Ministry of Health and district health departments to undertake their respective roles for full policy implementation.

I wish to thank the Medicines and Procurement Management Technical Working Group, the Task Team and the consultants who put this policy document together. NMP 2015 will provide direction for the Pharmaceutical Sector and all those concerned about ensuring that the people of Uganda have universal access to safe, efficacious, affordable and good quality medicines.



Hon. Dr. Elioda Tumwesigye, MP **Minister of Health** 

## GLOSSARY

For the purposes of this policy document the following terms will have the meanings given in the table below.

Term	Meaning / Interpretation in the context of the policy
Medicine/ Pharmaceutical product	The terms are used interchangeably and may include all or some of the following medicines, vaccines, medical devices, traditional and complementary medicines, health supplies, blood, biological products and other related healthcare products
Health Worker	Any person working in the health system who hold a health care qualification recognised by the government of Uganda
Pharmacy Professionals / Personnel	Any persons holding a formal qualification in pharmacy at either degree or diploma level

### ACKNOWLEDGEMENTS

The production of this policy document was made possible by the generous financial support of the Medicines Transparency Alliance (META). Coalition for Health Promotion and Social Development (HEPS-Uganda) provided funding that kick started the process.

On behalf of the Government of Uganda, I thank the World Health Organisation (WHO) Uganda Country Office and the Essential Medicines Department of the WHO Geneva for providing technical support and the consultants for the process.

I particularly want to thank all the members of the MoH Task Team for leading the process of the development of the NMP 2015 and the Uganda Health Supply Chain for the technical assistance provided. In a special way I would like to recognise the commitment and dedication of Dr. Fred Sebisubi, Joseph Mwoga, Thomas Ocwa Obua, Belinda Blick and the task team secretariat for ensuring that the process remained on track and that the policy document was delivered on time.

To all our partners and colleagues in the Ministry of Health, Government ministries, regulatory agencies, academia, professional associations, health development agencies, implementing partners and programmes, district health departments, central medicine warehouses, privatenot-for-profit (PNFP) sector, the private sector and civil society, who contributed to this process in one way or another, I thank you all.

Finally allow me to thank our consultants Dr. Hans Hogerzeil and Donna Kusemererwa who accommodated all our requests and stayed with the process to the very end.

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Morries Seru **Ag Ass. Commissioner Pharmacy** Ministry of Health

## ABBREVIATIONS

AMU	Appropriate Medicines Use
ARV/ART	Anti-retroviral/ Anti-retroviral therapy
CS (O)	Civil Society (Organisation)
EAC	East African Community
EMHS	Essential Medicines and Health Supplies
EMHSLU	Essential Medicines and Health Supplies List of
	Uganda
GMP	Good Manufacturing Practice
HF	Health facilities
HIV	Human Immunodeficiency Virus
HDP/HIP	Health Development Partners
HSDP	Health Sector Development Plan
JMS	Joint Medical Store
LMIS	Logistics Management Information Systems
MAUL	Medical Access Uganda Ltd
M & E	Monitoring and Evaluation
META	Medicines Transparency Alliance
MoH	Ministry of Health
NDA	National Drug Authority
NMRA	National Medicines Regulatory Authority
NDQCL	National Drug Quality Control Laboratory
NGO	Non-Government Organisation
NHP	National Health Policy

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NMP	National Medicines Policy
NMS	National Medical Stores
PD	Pharmacy Division
PFP	Private for Profit
PHC	Primary Health Care
PNFP	Private Not for Profit
SDP	Service Delivery Points
ТВ	Tuberculosis
СМ	Traditional and Complementary Medicine
UCG	Uganda Clinical Guidelines
UGX	Uganda Shilling
US	United States
UHC	Universal Health Coverage
UHMG	Uganda Health Marketing Group
WHO	World Health Organisation

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## BACKGROUND

The National Drug Policy of Uganda was first published in 1993. It was updated in 2002 to include new strategies to guide implementation and reflect legislative changes. The changes in the access to medicines landscape over the past decade have prompted Ministry of Health to revise the policy in 2015.

#### Context

In 2013, Uganda developed Vision 2040<sup>1</sup>, and is in the process of publishing the revised National Development Plan (NDP 2015)<sup>2</sup> and Health Sector Development Plan (HSDP 2015)<sup>3</sup> which together define the national and health sector development agenda over the short, medium and long term. The National Health Policy (NHP 2010) provides policy guidance for the health sector.<sup>4</sup>

Vision 2040 recognises that good health is instrumental for the socioeconomic transformation that Uganda seeks to achieve. The roadmap further proposes a paradigm shift for the health sector to empower households and communities to take greater control of their health by promoting healthy practices and lifestyles.

NDP 2015 highlights both preventive and curative services, emphasizing mass treatment of malaria; establishment of a national health insurance scheme; universal access to family

<sup>1</sup> Uganda Vision 2040. 2013. Available http://gov.ug/content/uganda-vision-2040

<sup>2</sup> Second National Development Plan 2015/16 – 2019/20. Strengthening Uganda's competitiveness for sustainable wealth creation, employment and inclusive growth. Draft for approval by parliament. April 2015

<sup>3</sup> Draft Health Sector Development plan 2015

<sup>4</sup> The Second National Health Policy 2010. Promoting people's health to enhance socioeconomic development

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planning services; health infrastructure development; reduction of maternal, neonatal and child morbidity and mortality; scaling up HIV prevention and treatment; and development of a centre of excellence in cancer treatment and related services.

The goal of the NHP 2010 is to attain a good standard of health for all people in Uganda in order to promote healthy and productive lives. The priority areas are: strengthening health systems in line with decentralisation; reconceptualising and organising supervision and monitoring of health systems at all levels; establishing a functional integration within the public and private sectors; and addressing the human resource crisis.

The goal of the HSDP 2015 is to accelerate movement towards Universal Health Coverage (UHC), with essential health and related services needed for promotion of a healthy and productive life. The sector hopes to achieve this through provision of equitable, safe and sustainable health services, addressing the key determinants of health through strengthening inter-sectoral collaboration and partnerships, ensuring financial risk protection of households, and enhancing the regional and global competitiveness of the health sector.

#### Rationale

Access to health care is a fundamental human right, spelt out in the Universal Declaration of Human Rights (UDHR) and recognised worldwide. However, without access to essential medicines the right to health cannot be fulfilled. WHO estimates that boosting economic growth and social development and scaling up existing interventions to fight disease could save over 10 million lives by 2015. Most of these interventions depend on essential medicines. According to WHO, access to medical products and technologies is one of the six building blocks of a health system, in addition to health work force, information systems, financing, service delivery, and leadership/ governance. Medicines, health supplies and vaccines are often the second largest expenditure in public health budgets.

Astudyof2,580 rural households in Uganda concluded that generally, poor people consider physical proximity, presence of skilled staff and medicines availability as the three key determinants when choosing a health care provider.<sup>5</sup> Sadly out of pocket expenditure on health in Uganda remains disproportionately high with the bulk of this expenditure going to medicines.

<sup>5</sup> Konde-Lule, J. et al. 2010. Private and Public health care in rural areas of Uganda. BMC Int Health, Nov 24; 10:29

#### **Development process**

MoH developed a concept note and terms of reference which were approved by the Medicines Procurement and Management (MPM) technical working group. Technical assistance was sought from WHO to guide the process; they also provided consultants. The Pharmacy Division, together with key partners, formed a Task Team to oversee the policy development process and guide the consultants. In order to ensure broad ownership of the policy, a highly consultative process involving a diversity of stakeholders was used. Individual stakeholder consultations, consultative meetings and workshops and a five day stakeholder retreat were conducted. Stakeholders had the opportunity to review the performance of the pharmaceutical sector under the old policy and to propose revisions. The new NMP provides a basis for the further development of the pharmaceutical sector taking into account the vision of the health sector and the national development agenda.

## SITUATION ANALYSIS

#### **UGANDA'S HEALTH SITUATION**

Uganda has a population of 34.9 million people (2014) and, with an average annual growth rate of 3.03%; it is projected to reach 42.4 million people by 2020. Communicable diseases such as HIV/AIDS, malaria, lower respiratory infections, meningitis and tuberculosis cause the highest numbers of life years lost in Uganda. However, non-communicable diseases (NCDs) are increasingly becoming a major burden. Life lost due to these conditions is rising significantly, with diabetes, self-harm, interpersonal violence and road injuries increasing at least twofold since 1990.

Health services in Uganda are provided by both public and private sectors. The private sector comprises of the PNFP, private-for-profit (PFP), and the traditional and complementary medicine practitioners (TCMPs). Ministry of Health is responsible for setting the policy and strategic direction while the local governments are responsible for service delivery under Uganda's decentralised health care delivery model. In 2013, Uganda had 4,478 health facilities, of which 65% were public, 20% PNFP and 14% PFP.<sup>6</sup>

Health services in Uganda are financed by Government, private sources and development partners. Only 11.6% of Government expenditure is spent on health which is far short of its commitment under the Abuja Declaration in which African governments pledged to spend at least 15% of their budgets on health. This means that considerable health expenditure (about 36%) is out-of-pocket, putting the poor and vulnerable at risk of catastrophic health expenditure<sup>7</sup>. A national health insurance scheme has been under discussion for over a decade however it is not yet in place.

<sup>6</sup> MoH, Health Facility Inventory 2013

<sup>7</sup> Individuals or households suffer "financial catastrophe" when they pay fees or co-payments for health care at levels that are so high that they have to cut down on necessities such as food and clothing, or are unable to pay for their children's education

#### THE PHARMACEUTICAL SECTOR

The pharmaceutical sector includes both public and private players. The private sector players are concentrated in urban centres and engaged mainly in sale of pharmaceuticals. MoH through the Pharmacy Division (MoH/PD), is responsible for the overall coordination of the sector, as well as for providing oversight for the NMP implementation. In addition, MoH/PD is responsible for quantifying national requirements for pharmaceutical products, harmonisation of the supply chain management system, as well as promoting rational use of pharmaceutical products.

The medicines situation in the public sector has improved significantly in the last five years in terms of product availability and quality. Average availability of tracer items in rural facilities has risen to around 85% in 2013/14, while order lead-time for public health facilities has decreased from 57 days five years ago to 37 days in 2013/14.

#### **Regulation and Quality Assurance**

The National Drug Authority (NDA) is the government body responsible for assuring the quality of all medical products in the country. It has a drug quality control laboratory that was prequalified by WHO in January 2015. The quality of pharmaceutical products imported into the country has significantly improved as evidenced by the drop in products failing quality tests from 11% in 2010/11 to 4% in 2013/14. Efforts being made within the East African Community (EAC) and at the continental level towards regional regulatory harmonisation are expected to further improve the quality of medicines circulating in the country. NDA reports an increase in the number of cases of adverse drug reactions from 268 in 2010/11 to 396 in 2011/12.<sup>8</sup> Hence, pharmacovigilance

<sup>8</sup> Ministry of Health, Draft Pharmaceutical Sector Policy Report, 2013.

activities need to be further supported and scaled up across the country. The legislative and regulatory framework is expected to become stronger when the ongoing review of the law establishing NDA is finalised with an expanded mandate for NDA.

#### **Medicines Financing**

Government financing for essential medicines and health supplies (EMHS) stood at UGX 219 billion in 2013/14, translating into a public per capita medicine expenditure of about US\$2.4. Out of this per capita spend (US\$2.4), a larger proportion goes to HIV, TB and malaria commodities, while a smaller proportion of about US\$1 goes to the rest of basic essential medicines. Donor support for medicine financing is significant, amounting to about US\$ 250 million in 2013/14, more three times the amount (US\$75 million) Government invested in EMHS in the same financial year. This support primarily goes to HIV, TB, reproductive health and malaria commodities. Uganda's heavy dependence on donor funds (valued at US\$6 per capita per year for medicines and vaccines) puts Uganda in a vulnerable position.

#### **Medicines Pricing**

The public sector obtains competitive prices for generic products at 40-50% lower than international reference prices.<sup>9</sup> Prices in the private sector are, on average, 3-4 times higher than those in the public and PNFP sectors. The country does not have pricing policies or price regulatory mechanisms. In 2013, Uganda enacted the Industrial Properties Act which fully recognised and incorporated flexibilities in the multilateral Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement). However, it is important for stakeholders to ensure that all pending intellectual property-related legislation incorporate TRIPS flexibilities.

<sup>9</sup> MSH Indicator Drug Price Guide 2013

#### **Medicines Selection and Quantification**

The Uganda Clinical Guidelines (UCG) and Essential Medicines and Health Supplies List of Uganda (EMHSLU) were updated in 2012. These are very important tools to guide selection, procurement, training, supervision and prescribing in the public and PNFP sector. Work has started on a National Medicines Formulary which will provide standard information on all the medicines on the EMHSLU. The national unit for quantification, procurement and supply planning guides and monitors the supply of key medical products in the system in coordination with development partners, technical programmes and warehouses.

#### Procurement, Warehousing and Distribution

National Medical Stores (NMS) is a government agency responsible for procuring, warehousing and distributing pharmaceutical products to public health facilities. Joint Medical Store (JMS), which is a faith-based organisation, does the same for PNFP health facilities. Medical Access Uganda Limited (MAUL), and Uganda Health Marketing Group (UHMG) are also significant players and complement government's efforts in pharmaceutical service delivery. All but UHMG provide "last mile" distribution to health facilities either directly or indirectly through third party logistics providers. This has improved distribution efficiency and quality through reduced lead times and improved security.

MAUL primarily distributes HIV related commodities, while NMS and JMS distribute a wide range of pharmaceutical products. UHMG distributes reproductive health commodities and other pharmaceutical products through the private sector at a subsidised price as part of a social marketing strategy. A web-based system is in use for health facility ordering of anti-retrovirals and other HIV commodities from the three central warehouses under a harmonised system in which each HIV treatment site is allocated to a specific warehouse.

An assessment of the physical condition of medicine stores in all public and PNFP health facilities was conducted in 2012/13. The findings of the assessment showed that 15% of the health facilities lacked medicine stores, and 29% did not have an appropriate designated dispensing room. Of those that had stores and dispensing rooms, 79% lacked shelves on which to properly store medicines; of those with shelves, majority need to have them replaced.<sup>10</sup>

#### **Medicines Use**

A recent World Bank report showed that only 20% of health workers could correctly diagnose four out of five common diseases at primary health care (PHC) level, and only 15% were able to correctly treat them.<sup>11</sup> Similarly other data shows that only about one-third of health workers are able to appropriately treat diarrhoea and upper respiratory tract infections.<sup>12</sup> Generic substitution is widely practiced, but not supported by law. Antibiotics are widely available without prescription and there are currently no systems in place to control the use of antibiotics or for routine surveillance of drug resistance in either the public or private sector.

<sup>10</sup> MOH, Health Facility Storage Assessment Report, 2012/13

<sup>11</sup> Service Delivery Indicators Initiative. Education and Health Services in UGANDA: Data for Results and Accountability. November 2013. Washington, DC: The World Bank.

<sup>12</sup> MOH 2015. Annual Pharmaceutical Sector Performance Report 2013/14

#### **Pharmaceutical Manufacturing**

The domestic manufacturing industry is still growing. Some incentives for local manufacturers are in place such as reduced import tariffs on pharmaceutical equipment and a 15% preferential rate in public procurement. However, it appears that the latter incentive has not yet been fully effected.

#### **Traditional and Complementary Medicine**

Traditional (also known as indigenous) medicines, though widely used in Uganda, are insufficiently regulated. There are no systems for licensing or tracking traditional healers or their products and as such a lot of unsubstantiated claims are made about traditional and complementary medicines (TCMs). Print media and radio are awash with advertisements from TCM practitioners who claim to have products to treat all kinds of conditions. Efforts to recognise, regulate and integrate TCM products and practices are yet to bear fruit.

#### **Human Resources**

The pharmacist-to-population ratio increased from 1.1:100,000 in 2010/11 to 1.6:100,000 in 2013/14. Many new positions for pharmacists have been created in the public service (from 77 in 2011/12 to 376 in 2013/14) but only 8% of the posts are filled. Although there has been an extensive training and support programme to train different professional cadres to function as medicines management supervisors countrywide, the need remains for district pharmacists to manage, supervise and support medicine management in lower level health facilities.

#### **Pharmaceutical Information Systems**

The existing logistics management information system (LMIS) is predominantly paper-based at facility and district levels, with some steps being made to introduce electronic-based systems. Computerised inventory management systems have been introduced in about one third of the hospitals. At national level, the central warehouses have computerised all their key functions – procurement, warehousing, finance, human resource and fleet management. However, there is currently no interface or linkage between the health facility logistics systems and the central warehouses. A pharmaceutical information portal is under development for users at all levels to easily access and analyse data from various data sources.

#### **Monitoring and Evaluation**

Capacity for monitoring and evaluation (M&E) has recently been increased in MoH/PD through staff secondments by implementing partners. Medicines management indicators are measured at facility level and regular reports are generated and disseminated. A national report on medicines management is produced quarterly and a sector performance report is prepared annually.

## GUIDING PRINCIPLES AND FOCUS AREAS

#### PRINCIPLES

#### 1) Universal Health Coverage

Government of Uganda intends to work towards the progressive realisation of the highest attainable standard of health by expanding health services to progressively achieve universal health coverage (UHC), using a primary health care approach. The NMP aims to support the achievement of universal access to comprehensive essential services. The medicines required for this effort will need to be clearly defined and quantified; and multiple financing strategies put in place to meet the needs for UHC.

#### 2) Equity and Efficiency

**Equity**: The policy aims to ensure that a range of EMHS are available for the people of Uganda based on need. More public funds are needed for EMHS because:

- (1) a large proportion of the population is currently without access and spending out of pocket;
- (2) donor funding may decline;
- (3) the population is growing and living longer;
- (4) people increasingly need more medicines including treatments for chronic non-communicable diseases; and
- (5) new essential medicines are relatively expensive.

**Efficiency**: The policy aims to ensure efficient use of the available limited resources. As more medicines are being supplied and distributed, better medicines management at district and facility levels becomes even more important to promote sound and cost-effective use of resources.

#### 3) Quality of Care

In line with the aspirations of the health sector, the policy aims to ensure that quality of care is emphasised in all applicable areas of policy implementation. Investments in quality of care will increase effectiveness of service delivery and improve patient safety.

#### **FOCUS AREAS**

Investments in the focus areas outlined below will drive development of the sector.

#### 1. Increased efficiency in utilisation of available funds:

Currently Government of Uganda provides support to PNFP facilities for EMHS through PHC grants. Setting up a mechanism similar to NMS' Budget Vote 116 through a not-state central warehouse such as JMS would ensure that a set proportion of funds is spent on EMHS procurement. The mechanism will also make it easier to ensure better vale for money.

#### 2. Improved medicines use:

All the efforts to provide funding and set up an effective supply system are futile if medicines are not used appropriately at the service delivery point (SDP). Therefore, a unit within Ministry of Health Pharmacy Department to provide stewardship, coordination and coherent leadership to appropriate medicines use activities is crucial. Lastly, efforts will be made to minimise stock piling, expiries, damages and other forms of waste so that the maximum benefit is obtained from the resources available.

#### 3. Improved pharmaceutical information systems:

Existing logistics management information systems (LMIS), at facility level and those at the central level, need to be interfaced in a way that allows free flow of information through the system. A prerequisite for this is that all LMIS must be available electronically. A national financial and commodity tracking system for all public and PNFP facilities also needs to be established. Other necessary pharmaceutical information systems will be established as required.

#### 4. Increased public financing for essential medicines:

Increased public financing is required to close the current gap in EMHS financing, to reduce the high levels of out-ofpocket expenditure and to prepare the financial basis for future subsidies for the social health insurance premiums. The extra funds are also needed to cater for the growing population, the increasing need for family planning, and for an ageing population with more demands for treatment of noncommunicable diseases.

## 5. Private sector participation and engagement in policy implementation:

MoH intends to proactively engage the private sector to identify areas in which they can contribute to achieving the policy goal.

#### 6. Establishing the post of district pharmacist:

In the current decentralised system, district pharmacists are key to monitoring the availability of EMHS, promoting efficient use of resources and assisting health facilities in strengthening the management of EMHS.

## 7. Strengthening the National Medicines Regulatory Authority:

A strong effective independent regulatory authority is required to ensure access while protecting the public from poor quality or otherwise harmful products. A special emphasis will be made to obtain government funding to protect the National Medicines Regulatory Authority's (NMRA's) independence.

#### 8. Governance:

MoH needs to strengthen and extend its oversight role over pharmacy professionals, practice, premises and products by among others:-

- Institutionalising the quantification and procurement planning and the M&E functions in the pharmacy division. Strengthening the M&E function will increase transparency and accountability of all the actors in policy implementation.
- Updating legislation to ensure that professional councils have the mandate for pharmacy practice.
- Further strengthening the human resource capacity in the Ministry of Health Pharmacy Division.

## INSTITUTIONAL ARRANGEMENTS AND IMPLEMENTATION

- Ministry of Health is responsible for the overall implementation of the NMP. Within the Ministry, the Pharmacy Division headed by the Assistant Commissioner, will take the lead providing guidance, coordinating, monitoring and evaluating the interventions of all the actors seeking to contribute to attainment of the policy goal.
- Other Ministry of Health bodies crucial to the implementation of this policy are NMRA, NMS and the Pharmacy Council.
- Equally important will be the linkages and inter-sectoral collaboration with other government agencies such as the Ministry of Finance, Planning and Economic Development (MoFPED), Health Monitoring Unit (HMU), National Environment Management Authority (NEMA), and Uganda National Bureau of Standards (UNBS).
- The non-government central warehouses JMS, MAUL and UHMG are expected to play a crucial role in ensuring access to quality affordable medicines.
- The entire health service delivery system including district health departments, hospitals, lower-level health facilities, Village Health Teams (VHTs) and Community Health Extension Workers will be part of the implementation process.
- The full engagement of diverse private sector entities including manufacturers, importers, distributors, retailers, hospitals and clinics will go a long way to ensuring achievement of desired outcomes.

- Ministry of Health is committed to engaging PNFP and PFP providers as far as possible to ensure effective implementation of the policy.
- Coordinating bodies such as the religious medical bureaus, Pharmaceutical Manufacturers Association, and Pharmaceutical Society of Uganda (PSU) provide will be entry points for effective engagement with private actors.
- Partnership with and engagement of civil society and communities is also recognised as an important prerequisite to achieving desired policy outcomes for the benefit of Ugandans.
- Collaboration with regional and international partners on issues such as harmonisation and standards development among others will be prioritised so as to harness the benefits and learning from partnership.
- A National Pharmaceutical Sector Strategic Plan will be developed by Ministry of Health to guide implementation of the policy. The plan will include the key interventions under the defined strategies, responsibilities, indicators, baseline data, and targets for M&E. This strategic plan will provide the basis for annual reviews and a mid-term evaluation on NMP implementation progress.

## **OVERALL POLICY GOAL**

The overall goal of the National Medicines Policy is to contribute to the attainment of the highest standard of health for the population of Uganda, by ensuring the availability, accessibility, affordability and appropriate use of essential medicines of appropriate quality, safety and efficacy at all times.

## POLICY OBJECTIVES AND STRATEGIES

## LEGISLATION, REGULATION AND QUALITY ASSURANCE

#### **Policy Objectives**

- 1. To provide a comprehensive regulatory and legislative framework that enables protection of health and ensures availability of safe and efficacious pharmaceutical products for the Uganda population.
- 2. To enhance the efficiency and effectiveness of regulatory agencies in ensuring compliance of pharmaceutical products, personnel, practices and premises with laws and regulations.

#### Justification

Medicine regulation is an essential function Government of Uganda, to promote the efficacy, safety and quality of pharmaceutical products in the country, and to protect the citizens of Uganda from the possible ill effects of unregistered, substandard or falsified products. The regulatory agencies propose and enforce regulations governing all aspects of the manufacture, importation, advertising and sale of pharmaceutical products, and regulate and license all products, personnel, practices and premises for pharmaceuticals.

- 1. Harmonise, amend/enact and enforce the legislation required to enable the effective regulation of pharmaceutical products, personnel, premises and practices.
- 2. Develop, update and enforce regulations on pharmaceutical products, personnel, premises and practices both in the public and in the private sector.
- 3. Strengthen the professional councils and ensure that their functions are aligned with other regulatory agencies.
- 4. Ensure the financial sustainability, independence, control and effective functioning of NMRA.

#### THE MEDICINES SUPPLY CHAIN

#### SELECTION, QUANTIFICATION AND PROCUREMENT

#### **Policy Objective**

- 1. To ensure that all medicines selected for use in the public health system are relevant to the priority needs of the population in line with the concept of essential medicines.
- 2. To establish and maintain reliable systems for regular and accurate quantification of medicine needs at all levels of the health system.
- 3. To procure quality assured medicines in a cost-effective and efficient manner.

#### Justification

The careful selection of medicines is an essential condition for defining the package of health care services for UHC. Accurate estimates of future medicine requirements are an essential condition for cost-effective procurement. These needs must then be reconciled with available financing. Efficient procurement mechanisms are vital for delivering the required package of medicines, and for cost-effective use of public resources.

- 1. Develop structures, criteria and processes to regularly assess priority health needs and revise the EMHSLU accordingly.
- 2. Regularly assess and quantify the national medicines needs.
- 3. Strengthen systems for efficient and effective procurement of medicines at all levels.

#### **INVENTORY MANAGEMENT**

#### **Policy Objectives**

- 1. To strengthen inventory management systems at all levels in order to maintain optimal stock levels throughout the supply chain.
- 2. To ensure that all medicines are appropriately, cost–effectively, safely and securely stored, distributed and accounted for at all levels of the health system.
- 3. To safely dispose of expired or otherwise unwanted medicines.

#### Justification

Good systems of inventory management at all levels are essential for preventing substandard or falsified products from entering the supply chain, preserving product integrity up to the point of use and minimising waste. The write-off and safe disposal of pharmaceutical products is a challenge for most health systems. If insufficiently planned and managed, stock piling of expired and unwanted products may block precious warehousing space for long periods, or re-appear on the market creating a health and environmental hazard.

- 1. Improve the infrastructure for storage at the central and peripheral levels.
- 2. Establish and maintain agreed minimum and maximum stocks at all levels.
- 3. Strengthen systems for ordering by service delivery points.
- 4. Strengthen systems for direct delivery to health facilities.
- 5. Strengthen systems for intra-health facility supply and distribution.

6. Institute and maintain a system to ensure the safe, effective and controlled disposal or destruction of expired or unwanted medicines.

#### LOCAL (DOMESTIC) MANUFACTURING

#### **Policy Objectives**

- 1. To promote the development and growth of domestic production of pharmaceutical products of assured quality, safety and efficacy.
- 2. To develop and empower the domestic pharmaceutical industry to satisfy national needs, and to promote economic and industrial development.

#### Justification

The development of a viable national domestic pharmaceutical industry has the potential to serve public health needs, to support economic and industrial development and promote national self-sufficiency. The challenge is to create a business model in which sufficient economies of scale can be achieved to justify the investment in good quality production, and still achieve competitive prices. Public support should focus on creating an enabling environment for the industry, and promoting export.

- 1. Establish and implement a system of tax incentives or subsidies for domestic manufacturers of essential medicines.
- 2. Encourage national and international procurement agencies to procure domestically produced essential medicines of good quality and competitive price.
- 3. Establish mechanisms to minimise imports of good quality essential medicines that can be manufactured in Uganda in sufficient quantities and at competitive prices.
- 4. Maintain regular and systematic inspections of premises and processes to ensure full adherence to licensing requirements and current Good Manufacturing Practice (cGMP).
- 5. Provide pathways for domestic manufacturers to gain additional regulatory certification, such as WHO prequalification of products.
- 6. Develop mechanisms to extend incentives given to Ugandan pharmaceutical manufacturers to other countries of the East African Community on an equal and reciprocal basis.
## MEDICINES USE

#### **Policy objective**

To ensure that end-users receive maximum therapeutic benefits from medicines through their scientifically sound and cost-effective use by prescribers, dispensers and consumers.

## Justification

Inappropriate use of medicines leads to suboptimal health outcomes and considerable economic waste. Inappropriate use is driven by many factors including lack of knowledge, medicine shortages, limited funds, lack of clinical guidelines, interrupted supplies, financial incentives, and pressure by patients and peers. Single interventions will not change this and a comprehensive programme with multiple interventions at various levels of the system targeting clinicians, dispensers, patients, and community is needed.

- 1. Establish a functional national Appropriate Medicine Use (AMU) programme with adequate human and financial resources.
- 2. Establish a national Medicines and Poisons Information Centre to provide timely, up-to-date, unbiased and evidence-based information to health workers and consumers.
- 3. Strengthen the national pharmacovigilance system for both the public and private sector.
- 4. Strengthen programmes for consumer awareness and promote community self-policing on medicines use.
- 5. Enforce the use of prescription forms as a basis of dispensing of all relevant medicines in both the public and private sectors.

# TRADITIONAL AND COMPLEMENTARY MEDICINE

#### **Policy objective**

To maximise the benefits of Traditional and Complementary Medicines (TCM) where possible and desirable and protect the public against their possible negative effects.

#### Justification

Nearly 80% of the populations in developing countries, including Uganda, use TCM for their primary health care needs due to its wide availability and accessibility. However, TCM practice remains a grey area and proving efficacy of most TCM products a challenge. Greater regulation to reduce risks from toxic ingredients and unsubstantiated claims of efficacy can go hand in hand with efforts to increase the contribution of TCM to achieving desired health outcomes.

- 1. Establish and operationalise an appropriate structure in Ministry of Health to promote, coordinate and monitor the implementation of multi-sectoral TCM activities.
- 2. Develop and preserve TCM knowledge and practices in their various forms.

## **MEDICINES FINANCING**

#### **Policy Objective**

To ensure the financing of adequate quantities of essential medicines for the people of Uganda, with equitable provisions for the poor and vulnerable, as well as cost-effective use of available resources.

#### Justification

stewardship includes The ensuring government's that pharmaceutical products are available as part of its essential health care strategy. However Uganda still has some way to go to realise its commitment to spending 15% of its budget on health as required under the Abuja Declaration. Medicines are the single most expensive out-of-pocket health expenditure item in Uganda and therefore constitute an enormous burden for the ordinary person. Significant commitments are required from government if people's medicine needs are to be met and undue burden on the public avoided. Ultimately systems for financing should ensure that: (1) the healthy subsidise the sick; (2) the rich subsidise the poor; and (3) the young subsidise the old.

- 1. Sustainably mobilise and efficiently use resources for financing quality medicines and systems for their equitable access and appropriate use.
- 2. Allocate the funds for procurement of essential medicines in an equitable manner, based on population served and health care needs, through both the public and private-not-for-profit health sector.

# **MEDICINES PRICING**

## **Policy Objective**

To ensure medicines are affordable to the individual and to the community.

## Justification

Current public financing for essential medicines is inadequate and therefore any efficiency gains are key to increasing access since they translate into more products. Efficient use is the first avenue to gain maximum benefit from limited resources ("more of the right medicines for the money available"). Additional public funding for essential medicines ("more money for medicines") can only be justified if available funds are used in a cost-effective and efficient way. Transparency about medicines prices and price mark ups is bound to help to drive prices down. In addition, future health insurance schemes will benefit from systems to monitor and promote affordable pricing. Special provisions are needed to deal with newly developed essential medicines which may be extremely expensive.

- 1. Establish and maintain mechanisms for ensuring affordable national public procurement prices, and consumer prices in the public and private sectors.
- 2. Ensure that national legislation takes cognizance of the World Trade Organisation (WTO)/TRIPS Agreement and exploits all its flexibility provisions.

# HUMAN RESOURCES DEVELOPMENT

#### **Policy Objectives**

To strengthen the human resource capacity in Ministry of Health Pharmacy Division, the public health sector and among other key stakeholders,<sup>13</sup> to undertake their roles and responsibilities in the implementation of the National Medicines Policy.

## Justification

The current human resource base for the pharmaceutical sector in Uganda is weak and under-resourced. Increased funding and stronger systems of in-service-training and support supervision are needed to ensure the efficient and effective use of the increased supply of essential medicines. A comprehensive human resource development plan is an important first step in this process so that guided evidence based investments can be made to improve the situation.

- 1. Prepare a national Pharmaceutical Human Resources Development Plan.
- 2. Establish and fill positions for the pharmaceutical personnel required to ensure effective implementation of the plan.
- 3. Strengthenthetrainingandinservicesupport of pharmaceutical professionals
- 4. Recognise and regularise, in the public sector, pharmacist specialties and super specialties (e.g. Clinical Pharmacy, Oncology, Pharmacoeconomics and Industrial Pharmacy).

<sup>13</sup> Stakeholders include regulatory bodies, professional councils, central warehouses, academic institutions, Districts other ministries, NGOs, provider organisations, the pharmaceutical industry and civil society.

# PRIVATE SECTOR ENGAGEMENT

### **Policy Objective**

To harness the synergies and opportunities in the private sector to maximise the implementation of the NMP

#### Justification

Both the PNFP and the PFP providers play an essential role in delivering health care and pharmaceutical services to the population, especially in the rural areas. The PFP sector also plays a crucial role in the local manufacture, importation and distribution of medicines country wide. Effective engagement of the private sector is an important prerequisite for the achievement of national health goals.

- 1. Promote public-private partnerships in the pharmaceutical sector, to address gaps in access to safe, efficacious and good quality EMHS.
- 2. Mainstream private sector participation in all aspects of policy implementation.

# **COMMUNITY ENGAGEMENT**

#### **Policy Objective**

To harness the synergies and opportunities in the community to maximise the implementation of the NMP.

## Justification

Health is made in the home. Achievement of the health goals and targets cannot be achieved without empowering people to take charge of their health. The empowerment of the population will include among others increasing community awareness about the licensing of medicines outlets, dangers of self-medication and the use of substandard and falsified products.

- 1. Mainstream community engagement in relevant aspects of NMP implementation.
- 2. Empower and promote strong community awareness on relevant medicines issues.

# NATIONAL, REGIONAL AND INTERNATIONAL COLLABORATION

## **Policy Objective**

To harness the synergies and opportunities available through national, regional and international collaboration to support the successful implementation of the NMP.

## Justification

Inter-sector collaboration is crucial to policy implementation because of the cross cutting nature of a lot of the issues that need to be addressed. Effective and efficient working relations with bodies such as the MoFPED, the Uganda Revenue Authority (URA), NEMA to name a few will be a pre-requisite for successful implementation. Efforts are also ongoing within the East African Community (EAC) on initiatives such as regulatory harmonisation and sharing technical expertise among others. Collaboration with a large number of international partners in health is ongoing but can be further strengthened. International information exchange and cooperation between universities and implementing agencies are widely practiced in many countries and are essential for progress in Uganda.

### Strategy

Facilitate ongoing collaboration and the exchange of information, skills, expertise and experience with international, regional, and national agencies, institutions and bodies.

## **RESEARCH AND DEVELOPMENT**

#### **Policy Objective**

To promote basic and applied research that enhances the effective implementation of the National Medicine Policy.

#### Justification

Operational research is an important tool to promote effective implementation of the NMP. Research projects can generate the evidence required for decision making about the interventions that are likely to return the best value. Involvement of pharmacy personnel in operational research creates a deeper understanding of the system's possibilities and challenges. Collaboration with universities on operational research allows staff who may have greater interest and more time to invest and there better results. Their scientific and independent attitude may yield useful insights and practical advice for strengthening pharmaceutical services. Basic research on the other hand is key to growth and development of the sector.

- 1. Identify, support and facilitate basic and operational research for key areas of policy implementation.
- 2. Promote appropriate research and development for new pharmaceutical products.

## PHARMACEUTICAL INFORMATION SYSTEMS

#### **Policy Objectives**

- 1. To establish systems to collect, store and track store management information on all pharmaceutical products, personnel and practices in line with the sectors information needs.
- 2. To ensure that data from all pharmaceutical information systems are available, accessible and utilised at all levels of the health sector.

### Justification

For a sound pharmaceutical sector and the goals of UHC to be achieved detailed information on medicines availability, equitable access, affordability, and use in practice has to be easily available. A comprehensive information system is crucial for proper implementation of the NMP as well as for monitoring and evaluating performance. Computerisation of all the information systems is key to ensuring accuracy, timeliness and ease of access to the information as well as facilitating linkages and analysis.

- 1. Establish and maintain systems to collect, process, analyse and share data on various aspects of implementation of the NMP.
- 2. Promote the use of computerised information systems at all levels.

# COORDINATION, MONITORING AND EVALUATION

## **Policy Objectives**

- 1. To strengthen government's stewardship function in coordinating, monitoring and evaluating the implementation of the NMP, in close collaboration with all relevant stakeholders.
- 2. To promote the use of results to inform decision making, policy refinement, performance improvement and organisational learning.

# Justification

The large national investment in medicines has such an impact on the quality of health care and represents such a high economic value that careful planning, management, monitoring and evaluation are needed, in order to ensure that the potential health benefits are realised and that economic waste is prevented. Progress towards the progressive realisation of the right to health and towards the two main objectives of the policy (equity and efficiency) need to be monitored on a continuous basis.

- 1. Strengthen the mandate and invest in providing Pharmacy Division with the necessary resources for coordinating, monitoring and evaluating the implementation of the NMP.
- 2. Establish functional plans and systems for monitoring and evaluation of the NMP at all levels.
- 3. Strengthen mechanisms for data quality improvement, access, dissemination and use at all levels.

#### NATIONAL MEDICINES POLICY 2015

ANNEX: List of Participants of National Retreat on National Medicines Policy and Associated Strategic Plan Held on 11th And 12th May 2015

No.	NAME	ORGANISATION	TITLE
1.	Lubyayi Lawrence	MoH/PD	M&E specialist
2.	Prof Paul Waako	Dusileine UN	dean
3.	Denis Okidi	UHSC	Tech. Advisor
4.	Philip Apira .O	UHMG	Head of Business
			DCO/SCM
6.	Dr. Mugadi Jairus	UPMB	Clinical Services
7.	Lameck Kachali	USAID	Supply Chain
			Systems Adv.
8.	Gladys Tugume	USAID-SUSTAIN	Deputy Chief of
			Party
10.	John Obicho	STAR-SW	
14	Lawrence Were	MoH-UNFPA	RHCSC
18.	Amuha Monica	MoH	STO
19.	Benson Obonyo	MSH/UHSC	Advisor
20.	Nakade Shamin	IDI	P.H.C
22.	Turyamureeba Colina	KCCA	H/Asst
24.	Pamela Achii	MoH	QPPU
25.	Arnold Kabbale	MoH	Pharmacist
26.	Agenorwot Anna F	IFRAD	Programmes
			Manager
27.	Okuna Neville Oteba	PB-MoH	Registrar
28.	Juliet Kitutu	UHSC	STO
29.	Samuel Balyejjusa	MoH	Pharmacist
30	Naymutale Peter	MoH	Deputy Registrar
	Michael C		AHPC
31.	Maynard	C. QCIL	Business manager/
			Chair
32.	Lubega Abdukarim	PACE	Pharmacist
33.	Anguyo Patrick	KCCA	DTCS
34.	Stella Nanyonga	Naguru Hospital	Senior Pharmacist
35.	Rogers Sekabira	Baylor Uganda	Pharm. Coordinator

#### NATIONAL MEDICINES POLICY 2015

36.	Ahimbisibwe E	MoH	PHE
37.	Paul Okware	NMS	HOSAO
38.	Myers Lugemwa	МоН	D/PM
39	Sseguya Simon	Mulago hospital	Principal pharmacist
40.	Richard Odoi Adome	Makerere Univ	
41.	Musuba B.F	OP/cab. secretariat	PPS
42.	Comfort Ssenyanwe	PSU	HC member
43.	Murungi A. Marion	IDI	Pharmacy Logistics Specialist
44.	Yiff Grusz	CHAI	CD
45.	Brian Arinitwe	HMU	As. Director
46.	Grace Kabaniha	WHO	NOP.HEC
47.	Joyce Tamale	UHMG	Managing director
48.	John Kamili	Cipla QCIL	FA manager
49.	Dr. Bagambe V	MoH/FCO	Q/A manager
50.	Amony M.Nancy	SCMS	SPA
51.	Nakagiri Emilly	MoH	RPMT
56.	Saudah A Kigande	Alive med	Lab Tech
57.	Mateeba .Tim	MoH	RH
58.	Olivia Kiconco	MoH-RPF	P. Officer RH
60.	Dr. Michael Oketcho	Uganda Heart Institute	Surgeon
61.	Lutoti Stephen	MoH	Research Officer
62.	Dr. Nambatya G.K	NCRI-MoH	Director of research
63.	Asiimwe Anthony	Buliisa	DTLS
64.	Aryeija Oren	Kabale	DMMS
65.	Sr. Josephine Oyela	Gulu	Pharmacist
66.	Mr.Opio Martin	Kitovu hospital	Medical supp
		Masaka	physician
67.	Dr.Opio Jimmy	Моуо	DHO
68.	Nanziri Ruth	Buikwe	MMS
69.	Muthoka .E.N	Tororo	Pharmacist
70.	Dr. Olaro Charles	Fortportal	
71.	Kaggwa David	Wakiso	pharmacist
72.	Dr. Wamasebu Gideon	Manafa	DHO
73.	Prof. P.Waako	Mbale	Dean
74.	Namboira Catherine	Arua	MMS

#### NATIONAL MEDICINES POLICY 2015

75.	Namulindwa Noeline	Kitgum	MMS
76	Samuel Mutyaba	MoH	Data manager
77	Obua Thomas	MoH	Sen Pharmacist
78	Onen Solomon	NDA	Regional Inspector
			of Drugs
79	Brenda Kasya	MoH	Drugs Officer
80	Walimbwa Aliyi	MoH	Senior Health
			Planner
81	Bamwoze Paul	MoH	IT officer
82	Albert Kalangwa	Access Global	Consultant
83	Dorothy Namuganga	Star-EC	Medical Logistics Officer
84	Dr. Bukoma Patrick	МоН	M&E Specialist
85	Richard Butamwita	CPHL-MoH	Tech. Advisor
86	Komakech Richard	NCRI-MoH	Research Officer
87	Senkungi Ismail	PSU	Pharmacist
88	Dr. Byakiika Sarah	MoH	ACUS QA
89	Mubangizi Emmanuel	Kabale district	SCO
90	Okot Amos	KCCA	Lab Tech
91	Apio Jacinta	St. Mary's Hospital Lacor	Pharmacist
92	Nabattu Nulu	UoMB	M&E
93	Okiror Adakuru	Rene Industries	Pharmacist
94	Nakagiri Emily	MoH	Pharmacist
95	Mildred Kabayaga	UPMB	Supply chain Officer
96	William Mutabazi	Baylor Uganda	Pharmacist
97	Namweseza Zam	APDL	Pharmacist
98	Mr. Oteba Martin	MSH/UHSC	DCoP
99	Rashid Settala	Medical Officer	
100	Talibita Moses	UNHCO	Legal Officer
101	Kalidi Rajab	MUK	Lecturer
102	Dr. Ebong	MoH	

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