A CRITIQUE OF THE LAW AND PRACTICE ON PROTECTION OF CONSUMER'S OF PHARMACEUTICAL PRODUCTS IN UGANDA

BY

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DECLARATION

I, Nabushawo Josephine do solemnly declare that this research report is my own original work and has not been submitted or, presented to any other Institution of learning for any academic purposes for the award of a Bachelor degree or its equivalent, nor has it been published anywhere by anyone.

Signed .....

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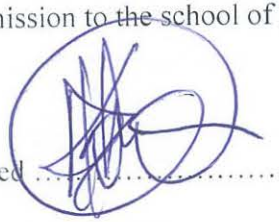
Date .....

APPROVAL

This research has been under my supervision as a University Supervisor and is now ready for submission to the school of law of Kampala international university for approval.



Signed ..... Date 23/7/18

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TABLE OF CONTENTS

GENERAL INTRODUCTION

1.1 Background of the study

Consumer protection is a general concept that involves protecting people from buying things and services that are unsafe or fraudulent. Consumer protection is one of the major social policies promoted by any modern state[1]. Because of the importance it represents for the contemporary economy, it is an independent policy, with own objectives, priorities and tools. The speed which events follow each other today is increasingly. That's why consumerism is expanding more and more too all the sub-branches of the economy. In this way, the scope and action of consumer protection is extremely large, reaching all the economic sectors[2].

Protection of consumers of pharmaceutical products means the attempts to protect the people or consumers that are charged with the responsibility of consuming the pharmaceutical products that fall in the human and non human pharmaceutical products. In Uganda, legal provisions exist for controlling the pharmaceutical market[3]. Laboratory exists in Uganda for quality control testing[4]. However, the NDA also contracts services elsewhere. This is done for microbiological, public health and herbal product testing. The protection of the consumer of pharmaceutical products is undertaken based on the legal attributes that countries establish in the management of the country for the regulations of the pharmaceuticals in the country.

The EAC, like other sub-Saharan countries, relies largely on imports for pharmaceuticals. These imports are mainly from China and India. Where pharmaceutical manufacturing does occur, this involves the production of noncomplex, high-volume, essential products such as basic analgesics, simple antibiotics, and vitamins. Kenya has the most developed pharmaceutical manufacturing sector in the region[5].The regional pharmaceutical sector consists of manufacturers, distributors, wholesalers, retail pharmacies, hospitals, and clinics. Pharmaceutical manufacturers are either local or multinationals. Few multinationals have local manufacturing

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[1] http://www.faqs.org/health/topics/6/Consumer-protection.html
[2] http://www.nabp.net/programs/consumer-protection/buying-medicine-online
[3] National Drug Authority (NDA). National Drug Act. 1993. Available at:http://www.nda.or.ug/drug-reg.php. Accessed March 20, 2018.
[4] National Drug Authority (NDA). National Drug Authority Quality Control Laboratory (NDAQCL). 1995. Available at: http://www.nda.or.ug/lab.php. Accessed March. 24 2018
[5] East African community. (2012). EAC regional manufacturing plan of action, 2012 – 2016. Arusha: EAC.

plants; rather there are local agents who distribute their products. Multinational pharmaceutical companies also have scientific and marketing offices.

All countries, apart from Rwanda, have distinct national medicines policies (NMPs). Rwanda's policy is embedded in the National Health Policy. Burundi, Kenya, and Tanzania (Zanzibar) have updated NMPs. Tanzania (Mainland) has a draft policy that was presented in 2014, but has not yet been approved. Uganda is currently revising its NMP, which is expected to be completed in 2015. Rwanda started work on its NMP in 2009, but this is yet to be approved[6].The time taken for the review and approval of NMPs is long. Timelines span 24 years, that is, 1991–2015 (Tanzania Mainland); 13 years, that is, 2002–2015 (Uganda); 6 years, that is, 2009–2015 (Rwanda). Kenya has managed to produce three revisions over the period 1994–2012; Tanzania (Zanzibar) has produced two NMPs from 1991 to 2014; Uganda is on its third revision; and Rwanda is still developing its first policy. These timelines highlight the varying capacities and challenges faced by the Partner States in the development, review, and revision of NMPs. The scope of existing NMPs of Partner States generally covers pharmaceuticals for human and veterinary use[7] as well as herbal products. The updated policies of Kenya and Tanzania (Zanzibar's) have extended scopes to also include medical devices and technologies, food products, tobacco products, cosmetics, and emerging health technologies.

The laws governing the consumer pharmaceutical products in Uganda is envisaged in the laws of Uganda such as the National drug authority Act, 2006.[8], the food and drugs act Cap 278 in the laws of Uganda. The laws governing the consumers of pharmaceutical products are in full operations though the effectiveness of the laws in Uganda are present the investigative nature of the environment regarding the monitoring of the pharmacies in Uganda that is limited and has accounted for the presence of fake medicines in the pharmacies that are presenting a measure for the evaluation of the consumer protection mechanisms.

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing. Legal provisions exist requiring importation of

[6] hera. EAC medicines policy, legal and regulatory frameworks. Report. Sept 2015.
[7] East African Community. One people one destiny. www.eac.int. Accessed 12 February 2018.
[8] Section , 12 of the national drug policy and authority act , Cap. 2006

medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry[9]. In Uganda, legal provisions exist requiring manufacturers to be licensed[10]. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices. Good Manufacturing practices are published by the government. Legal provisions exist requiring importers, wholesalers and distributors to be licensed. Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices.

Legal provisions exist requiring pharmacists to be registered. Legal provisions exists requiring private and public pharmacies to be licensed[11]. National Good pharmacy Practice Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published In Uganda, legal provisions exist for controlling the pharmaceutical market[12]. A laboratory exists in Uganda for Quality Control testing. The laboratory is a functional part of the MRA. However, the NDA also contracts services elsewhere. This is done for microbiological, public health and herbal product testing. The NDA laboratory preparing for the collaboration with the WHO prequalification Program.[13].

1.2 Statement of the Problem

Consumer protection constitutes a high degree of requirements and a fundamental composition of commercial law requirements in a country. Uganda has a lot of institutions and the legal framework that guide the consumers from consumption of the defect products including the pharmaceutical products. There exist the national drug policy of Uganda was first published in 1993 that guide the usage of the pharmaceutical products (UNBS, 2010). This law 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. The legal framework in the country seems to be in existences though with limited in operations with regard to enabling the consumers of pharmaceutical

[9] National Drug Authority (NDA). National Drug Act. 1993. Available at: http://www.nda.or.ug/drug-reg.php. Accessed February 20, 2018.
[10] Ibid
[11] http://law.jrank.org/pages/12503/Consumer-Protection.html
[12] Ibid
[13] National Drug Authority Uganda. 2011. Available at: http://www.nda.or.ug/index.php. Accessed February 20. 2018.

products attain a full function (MOH, 2014). There exist complaints from consumers on the quality of pharmaceutical products in both government and private pharmaceuticals in the country. The status quo of the consumer protection despite the legal framework raises issues that need to be addressed if the consumers have to attain value of the products quality. It was based on this that the researcher set to critically analyze the existing legal framework on pharmaceutical products in Uganda in order to provide remedy for the country.

1.3 Objectives of the study

1.3.1 General Objective

To examine the existing laws and practice on protection of consumers of pharmaceutical products in Uganda.

1.3.3 Specific Objective

1) To examine the legal provisions on consumer protection of pharmaceutical products in Uganda.
2) To explore the effect of contributions of the Food and Drugs Act and National drug policy and Authority Act, Cap. 206 on consumer protection of pharmaceutical products.
3) To establish the legal challenges to consumer institutional framework on protection of pharmaceutical products in Uganda.
4) To make recommendations on how the challenges of consumer protection can be dealt with

1.4 Research Questions

1) What are the legal provisions on consumer protection of pharmaceutical products in Uganda?
2) What is the effect of contributions of the Food and Drugs Act and National drug policy and Authority Act, Cap. 206 on consumer protection of pharmaceutical products?
3) What is the legal challenges to consumer institutional framework on protection of pharmaceutical products in Uganda?
4) What are the recommendations on how the challenges of consumer protection can be dealt with?

1.5 Scope of the study

1.5.1 Geographical Scope

The study was conducted in the Uganda environment assessing the legal provisions provided under the Ugandan context. The critical documents review included those of national drug policy and authority provided under the assessments.

1.5.2 Content Scope

The study covered an assessment of the legal provisions on consumer protection of pharmaceutical products, legal challenges to consumer protection of pharmaceutical products in Uganda.

1.5.3 Time Scope

The study was conducted evaluated a period of 7 years from 2009 to 2017. The study findings provided that can provide information necessary for the effective conducting of the study.

1.6 Significance of the study

The research findings are significant to the following;

Organizations especially NDA and Pharmaceutical companies will be helped in attaining and adopting more realistic approaches to consumer protection with regard to employees in the organizations.

There is no doubt the result may contribute to the existing laws on consumer protection of pharmaceutical products in the Ugandan environment.

The study will explore the loopholes in the protection of consumers of pharmaceutical products in Uganda and provide remedy that will enable the government and other institutions in improving the quality of the pharmaceutical products.

1.7 Literature Review

The pharmaceutical sector presents a unique sector with access to almost unlimited amounts of information on the global scale (Darrouch and Miles, 2011), but effective decision making remains a momentous challenges. There is meanwhile an impressive history of effective decision making practices, models and approaches that have traversed the civilization journey from which contemporary managers can borrow useful insights. The expansive wealth of information on how

earliest people made decisions and how similar approaches were meticulously accomplished when man began living in organized societies shed much light on how contemporary decision making can be improved.

The pharmaceutical industry in any country contributes immensely to improving the citizen's health outcomes and productivity and life expectancy. A report by Cheraghali (2010) shows that Americans and British have a well developed pharmaceutical industry, that contributes to their high quality of life (i.e. life expectancy in United Kingdom is at 78.1 for men and 82.1 for women; deaths under 45 yrs dropped from 50% in the 1900s to 4.4%; cardiovascular deaths at 75 yrs reduced by 44%, chemotherapy saving up to 1,600 lives of cancer a year). In comparison to some countries like Iran, which still have a relatively poorly developed pharmaceutical industry, limited to the formulation of cheap and fairly old medicines that cannot cure many diseases, their life expectancy and productivity is low. It is uncontestable that the pharmaceutical sector develops produces, and markets medicines, medical equipments, drugs, cosmetics, and dietary supplements, for both human and veterinary use.

In Uganda's context, Omaswa (2012) demonstrated how access to health services, qualified healthcare staff and medicines were necessary components of any healthcare system. However, the issue of medicines presented a special importance for various reasons: They save lives, improve health, promote trust and participation in health services. Serutoke (2012) emphasized that; communities will quite understandably equate the quality of healthcare primarily with the availability of basic essential medicines and drugs.

THE PHARMACEUTICAL SECTOR IN UGANDA

According to the Uganda Pharmaceutical Manufacturers Association (UPMA), Uganda's pharmaceutical market has an estimated value of US$ 276 million, of which 90 per cent of the medicines are imported, mainly from India and China, and 10 per cent produced by local manufacturers. The imported medicines and health supplies account for 5.4 per cent of Uganda's total imports (UIA, 2009).

Uganda has a total of 11 licensed local pharmaceutical manufacturers, 477 registered pharmacies and over 4,370 chemist shops (NDA, 2009). As of 2006, the country had 114 hospitals, 60 of which were public, 46 private not for profit or FBO, and eight private (UNBOS, 2009).The

National Medical Stores (NMS) are responsible for the procurement, storage and distribution of medicines and health supplies for the public sector, while the private sector is served through a chain of wholesale and/or retail pharmacies, chemist shops, and private clinics. Unfortunately, there remains a lot of public outcry about the inefficiencies in Ugandan's pharmaceutical services sector.

The World Health Organization (2010) indicated existence of so many unlicensed pharmacy traders on the market, fake / adulterated drugs being sold in pharmacies and clinics, and involvement of un-qualified personnel in the dispensation of pharmaceutical services. The high prices of pharmaceutical products in Uganda compared to other countries in the region leads to a situation of smuggling in drugs from neighboring countries. Yet, the available information ought to have guided effective decision making in the regulation, management and administration of the sector. One therefore wonders whether there is any causal relation-ship between information management and effective decision making in the pharmaceutical sector. This study is being undertaken in this context to examine how information management and effective decision making in the pharmaceutical sector in Uganda are related. Counterfeit drugs constitute probably the single biggest challenge to the pharmaceutical industry in Africa. Such drugs are defined by the World Health Organization as "deliberately fraudulently mislabeled with respect to identity and source. It is believed that more than half of the drugs sold in Africa are fake (Mclaughin, 2012).

In 1993, Uganda formulated the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act (2000 Edition). The Act established a National Drug Authority (NDA) to contribute to the attainment of a good standard of health by the population, through ensuring the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety, and efficacy. The role of NDA is also embedded in the National Veterinary Drug Policy, whose vision is to have quality veterinary drugs accessed by all stakeholders for sustainable animal health and production. According to the NADP/A Act, this institution is charged with the development and regulation of pharmacies and drugs in the country, control to the importation, exportation and sale of pharmaceuticals, control to the quality of drugs, promotion and control to the local production of essential drugs,

encouragement to research and development of herbal medicines, establish and revise professional guidelines and dissemination of information to health professionals and the public, provision of advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy.

MoH (2010) indicates that over the last 12 years, the Government of Uganda has developed two comprehensive National Health Policies (NHP); National Health Policy I (NHP I) in 1999, and National Health Policy II (NHP II) in 2009. Both these policies are aimed at increasing access to essential medicines as part of national efforts to deliver the Uganda National Minimum Healthcare Package (UNMHCP), which puts particular emphasis on management of communicable diseases, especially HIV/AIDs, malaria and tuberculosis.

Consumer Protection

The UN Guidelines for Consumer Protection provide a framework for governments to use in formulating legislation and policies. Governments were called upon to develop, strengthen and maintain a strong consumer policy to protect their population as consumers. Governments were expected to provide a legal basis for enforcing basic consumer rights, with a minimum of consumer protection legislation covering physical safety, promotion and protection of consumer economic interests, standards for the safety and quality of food and service, distribution facilities, redress and education information programs. Governments would also provide the necessary machinery for the enforcement of such rules.

The Guidelines observe that governments should set their own priorities for the protection of consumers in accordance with the economic, social and environmental circumstances of the country and the needs of its population, bearing in mind the costs and benefits of proposed measures. The Guidelines also require Governments to pay attention to the issue of vulnerable consumers, insisting that special care should be taken to ensure that measures for consumer protection are implemented for the benefit of all sectors of the population, particularly the rural population and people living in poverty.

Medicines availability is a challenge for low income countries due to lack of resources for medicines and health supplies, poor infrastructure and lack of workforce capacity. Following the establishment of the WHO Model Essential Medicines List (EML) in 1977, many countries have adopted this concept in order to priorities their medicine needs (Laing, Waning, Gray & Ford, 2010). Under the Ugandan National Drug Policy essential medicines are a means of ensuring that safe, efficacious and good quality medicines are available and accessible at all times and that they are affordable and used appropriately (MOH, 2012). The Ugandan Ministry of Health's first national EML list (EMLU) was released in 1991 and is updated approximately every five years, most recently in 2012. Although essential medicines should be freely available at public health facilities this is not necessarily the case forcing the population to rely on pharmacies and drug shops in the private sector, particularly for obtaining life-saving medicines. Few studies have looked at the availability of essential medicines in private outlets. In this study, we conducted a survey of the availability of six tracer medicines listed on the EMLU at private drug retail outlets in Uganda (Birungi, Mugisha, Nsabagasani, Okuonzi & Jeppsson, 2011).

Uganda's pharmacy and drug retail outlets

The public healthcare system is organized in four tiers: community health teams at the local level, health centers at the parish level, sub-county and constituency up to the district level, and regional and national referral hospitals which can provide comprehensive, specialist care. In the public sector, vertical disease programs provide medicine consumption data and forecasts for malaria, tuberculosis and HIV/AIDS. However, the private sector makes up nearly 50% of healthcare delivery in Uganda and is subdivided into formal and informal sectors. The formal sector is comprised of private pharmacies, drug shops, private clinics and private hospitals (Laing et al, 2002). The informal sector consists of general merchandise shops and traditional practitioners. Private retailers, both formal and informal, are the major sources of medicines for patients and require licenses from the National Drug Authority (NDA) head office or Regional Inspectors of Drugs (Konde-Lule, Gitta, Lidnfors, Okuonzi & Onama, 2010).

Medicine registration and scheduling

Most drugs that are authorized for use in Uganda are listed on the National Drug Register (. Furthermore, the National Drug Policy and Authority Act 1993 provide information about which

drugs can be sold by pharmacies and drug shops (Tumwikirize, Ekwaru, Mohammed, Ogwal-Okeng & Aupont, 2012). Medicines are classified into four schedules: Class A drugs (or narcotics) may be sold by retail only with a prescription and may be supplied only by a registered pharmacist or licensed pharmacy under specific guidelines issued by the NDA; Class B drugs (or controlled drugs) are divided into two groups: group I (prescription-only medicines) may be supplied only with a prescription and group II (pharmacy-initiated medicines) may be supplied without a prescription only by a registered pharmacist or licensed pharmacy; Class C drugs (or licensed/over-the-counter drugs) may be sold by a person or company operating a licensed pharmacy or by a licensed drug seller (according to the specifications of the license); the fourth schedule identifies medicines and articles exempt from regulation by the NDA. While pharmacies can avail all classes of medicines, drug shops are restricted to Class C drugs.

Pharmacy and drug shop licensing and the law

By law, the NDA must register all drugs shops and pharmacies annually. However, the licensing of pharmacies and drug shops is managed at the regional authority offices. Pharmacies predominantly exist in urban areas, while drug shops are distributed evenly in rural areas [15]. Qualitative studies in Uganda have highlighted problems associated with drug outlets including; inadequate information given to patients, irrational drug sales, or the inappropriate use of medicines and illegal sale of prescription drugs (Stanback, Otterness, Bekiita, Nakazyiza & Mbonye, 2011).

Registration of medicines with the NDA is a legal requirement however unregistered products were found in surveyed drug shops and pharmacies including: 1 fluoxetine, 1 metformin, 2 oxytocin, and 5 rifampicin. In this study it is mainly brands of rifampicin, a highly regulated drug, that were unregistered. Unregistered brands of rifampicin were found in 6 pharmacies surveyed in Kampala (13% of total) and 1 pharmacy each in Mbarara and Bundibugyo. Pitocin was found in 20% of drug shops surveyed in Bundibugyo and 25% of drug shops surveyed in Mbarara. None of which had the facilities for cold chain storage. The presence of unauthorized drugs on the market has been attributed to the illegal operation of drug outlets (Konde-Lule, Gitta, Lidnfors , Okuonzi & Onama, 2010. Uganda's porous borders allow illegal products to reach the market.

1.7.3 Challenges to consumer protection

Inadequate linkages: Other than NEMA, the institutions set up in the legislations are by large compartmentalized without legal requirement for them to consult or work together on any subject. The cooperation that exists is informal. As a result they have inadequate linkages, poor communication and coordination between them and this leads to unharmonised and incompatible data and contributes to ineffective enforcement. Consumer protection as the subject of concern on the other hand demands multi-sectoral and multidisciplinary and synergic action. This situation calls for legal and administrative improvement of linkages and therefore calls for a major exercise to identify, revise, amplify, consolidate, harmonize and make specific the necessary linkages in the laws.

Patchy coverage: Despite the good effort and intentions resulting in existence of reasonable provisions, the old of the laws carry the thinking of the 1950s; a time when the technology, environment and health effects had not become so prominent and were apparently innocent. Correspondingly the legislation is, in many areas, outdated and patchy in dealing with present problems in consumer protection[14].

Inadequate coordination: Consumer protection management operations involve many independent participants usually operating in a situation of urgency. They therefore need a high level of co-ordination. This system is inadequate. Consequently it is necessary to develop a system with high ability to co-ordinate these operations.

Institutional Weaknesses: The national competent authority especially for an importing country should have the ability to enforce and take action on any part of the chain based on adequate legislation. It should take all necessary steps to insure the integrity, impartiality and independence of official inspection systems and officially recognized inspection systems and to ensure that the inspection programs contained in national legislation is delivered to a prescribed standard. The main competent authorities are the Ministry of Trade, Tourism and Industry; The Ministry of Health; The Ministry of Agriculture, Animal Industry and Fisheries; The Ministry of Gender, Labour and Social Development; and the NDA, UNBS, NEMA. All these are

[14] Ministry of Health. Draft Pharmaceutical Sector Policy Report, 2013.

inadequately funded, inadequately staffed, inadequately equipped and so they lack the capacity to implement the laws in place[15].

1.8 Methodology

The research employed a doctrinal qualitative research design. The doctrinal research is concerned with legal prepositions and doctrines. The sources of data are legal and appellate court decisions. The doctrinal research was conducted through reviewing the different legal documents and articles concerning the issues of consumer protection in the pharmaceutical setup. The study employed qualitative methods due to the nature of the study. Various secondary data such as text books, case law, dissertations, Acts of the parliament, international treaties and government policies were consulted for purposes of compiling and establishing the legal framework the consumer protection of pharmaceutical products in Uganda.

1.9 Organization Layout

The research consist of five chapters,

The chapter one introduced the problem, background, problem statement, objectives, research questions, scope, significance of the study, literatures that are available, reviewed the problem and some other preliminary information and it discusses the problem and its scope and the methodology of the study.

Chapter two included the general overview of the international instruments, continental, regional systems in consumer protection on pharmaceutical products.

The third chapter provides an analysis of the legal and institutional framework on consumer protection of pharmaceutical products in Uganda.

Chapter four dealt with research findings and analysis in line with the research objectives and chapter

The fifth objectives included summary of findings, recommendations and conclusions.

[15] Uganda national bureau of standards report, 2010

CHAPTER TWO

INTERNATIONAL, CONTINENTAL, REGIONAL PROVISIONS ON CONSUMER PROTECTION OF PHARMACEUTICAL PRODUCTS.

2.0 Introduction

This chapter presents the views regarding the overview of the international instruments, continental, regional systems in consumer protection on pharmaceutical products. It explores the provisions and how they ensure protection of pharmaceutical products.

2.1 International instruments

The United Nations specialized agencies, the World Trade Organization (WTO), the Group of 20 (G20), the Organization for Economic Cooperation and Development (OECD), and regional bodies such as the Association of Southeast Asian Nations (ASEAN), the Asia Pacific Economic Cooperation (APEC), the African Union (AU), the European Union (EU), and the Organization of American States (OAS), are among intergovernmental organizations having developed, inter alia, agreements, resolutions, directives and guidelines, that have a bearing on consumer protection. This section will deal specifically with the UNCGP that have been adopted by the United Nations General Assembly by consensus, as a 'valuable set of principles' 18 for consumer protection[16].

The United Nations Guidelines for Consumer Protection were adopted by consensus by United Nations General Assembly in resolution 39/248 of 16 April 1985. This followed a long campaign by consumer associations in many countries, with Consumers International (formerly known as the International Organization of Consumer Unions) having called upon the United Nations to prepare a 'Model Code for consumer protection ' at its World Congress in Sydney in 1975. In 1977, the Economic and Social Council (ECOSOC) directed the Secretary-General to prepare a survey of national institutions and legislation in the area of consumer protection. In 1981, ECOSOC requested the Secretary-General "to continue consultations on consumer protection

[16] On March 15, 1962, President Kennedy presented a speech to the United States Congress in which he extolled four basic consumer rights; safety, information, choice and the right to be heard, later called the Consumer Bill of Rights.

with a view to elaborating a set of general guidelines for consumer protection, taking particularly into account the needs of the developing countries[17].

The revised UNGCP of 2015, annexed to resolution 70/186 and an integral part thereof, make specific reference to the needs of developing countries, including the setting of the Sustainable Development Goals (SDGs) and the preceding Millennium Development Goals (MDGs). The Intergovernmental Group of experts on Consumer Protection Law and Policy is established to operate under the auspices of UNCTAD as the institutional machinery of the UNGCP. The revised UNGCP extend their scope to State-owned enterprises and introduce four new 'legitimate needs' into Guideline 5. Completely new sections are inserted on principles for good business practices and national policies for consumer protection, electronic commerce (Guidelines 63-65), and financial services. The pre-existing Section E on measures enabling consumers to obtain redress is renamed dispute resolution and redress and is expanded to reflect the rapid evolution of such mechanisms and now includes references to debt and bankruptcy

Resolution 70/186, which precedes the UNGCP, reaffirms: "the Guidelines as a valuable set of principles for setting out the main characteristics of effective consumer protection legislation, enforcement institutions and redress systems, and for assisting interested Member States in formulating and enforcing domestic and regional laws, rules and regulations that are suitable to their own economic and social and environmental circumstances, as well as promoting international enforcement cooperation among Member States". It goes on to recognize that: "consensus exists on the need for common principles that establish the main characteristics of effective consumer protection legislation, enforcement institutions and redress systems"; and that consumer protection requires a "robust legal and regulatory framework for consumer protection.

The Guidelines themselves are less explicit, pointing out that (Guideline 2): "consumer protection policies include Member States' laws, regulations, rules" wherein enterprises should obey the law (Guideline 9) and that there need to be 'legal systems' (Guideline 16) or 'measures' (Guideline 37) in place. Political rights, also known as first-generation rights, but a range of economic, social and cultural rights that are sometimes referred to as second-generation rights.

[17] Resolution II A/70/470/Add.1 Distribution December 15 2015, adopted by UNGA December 22nd 2015. NB: The term 'UNGCP' is used to apply to the full set of Guidelines in this manual. Sections of the UNGCP are referred to as appropriately.

To complement both sets of rights, the trend has been to include the right to development, known as third-generation rights. One theme explored here, relevant to the evolution of rights, is that much legislation relevant to consumers is not explicitly related to consumers.

Chapter 4 shows how sectoral legislation and policy has become ever more cognisant of the consumer protection dimension, often going beyond retail 'shoppers rights' and taking into account access issues, which may well include 'non-shoppers i.e. unserved populations. This issue of access is the subject of numerous United Nations declarations and most comprehensively by the MDGs and the SDGs, both of which have been explicitly recognized by the UNGCP. These goals are discussed in chapter 18 of this manual. Many such access rights are expressed in national constitutional provisions. In 2008, UNCTAD reported that the constitutions of at least 24 countries provided for consumer protection, often linked with competition policy, as with the Mexican Constitution for example.[18] UNCTAD reported in 2013, that "in many cases, consumer protection has been constitutionally enshrined and some countries have recognized consumer rights as human rights.[19] Egypt, Poland and Switzerland and the recognition of the human rights dimension by the Mexican Supreme Court in 2012. Analysis of constitutional provisions indicates great differences in content, which can be synthesized as emphasizing 'high level' principles.

The European Union Consolidated Treaty on the Functioning of the European Union states: 'In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organize themselves in order to safeguard their interests.[20] The European Charter of Fundamental Rights sets out, in Article 38 (under the title of Solidarity), the requirement for a high level of consumer protection: 'Union policies shall ensure a high level of consumer protection.' Other rights relevant to the legitimate

[18] Article 28 applies consumer protection through its anti-monopoly measures. With exceptions, (such as State-provided services) monopolies are forbidden

[19] Implementation Report on the United Nations Guidelines on Consumer Protection. 1985–2013. Note by the UNCTAD secretariat, April 2015: See in the case of the Supreme court of Mexico: See - http://www.consumidor.gob.mx/wordpress/wp-content/uploads/2012/04/SENTENCIA_AMPARO_MEXICANA.pdf

[20] Article 169.1of the Consolidated version of the Treaty on the Functioning of the European Union; 26.10.2012 C 326/47.

needs are set out elsewhere in the Charter under Respect for Privacy (Article 7), Protection of Personal Data (Article 8), Freedom of Association (Article 12), Access to Health Services (Article 35) and Public Utility Services (Article 36). Such high level principles are often considered more appropriate for constitutional content than detailed provisions

Governments should develop or maintain adequate standards, provisions and appropriate regulatory systems for ensuring the quality and appropriate use of pharmaceuticals through integrated national drug policies which could address, inter alia, procurement, distribution, production, licensing arrangements, registration systems and the availability of reliable information on pharmaceuticals. In so doing, Governments should take special account of the work and recommendations of the World health organization on pharmaceuticals. For relevant products, the use of those organizations certification scheme on the quality of pharmaceutical Products Moving in International Commerce and other international information systems on pharmaceuticals should be encouraged. Measures should also be taken, as appropriate, to promote the use of international nonproprietary names (INNs) for drugs, drawing on the work done by the World Health Organization[21]. In addition to the priority areas indicated above, Governments should adopt appropriate measures in other areas, such as pesticides and chemicals in regard, where relevant, to their use, production and storage, taking into account such relevant health and environmental information as Governments may require producers to provide and include in the labeling of products.

2.2 Continental conventions on protection of consumers of pharmaceutical products

Recognizing the efforts of the African Union (AU), Regional Economic Communities (RECs) and Regional Health Organizations (RHOs) to mobilize human, financial and material resources and continental expertise to deal with the outbreak of EVD; and subsequent establishment of regional Expert Working Groups (EWGs) on Clinical Trials Oversight in East African Community (EAC) and the Economic Community of West African States (ECOWAS) as part of the implementation of the 24th Ordinary Session of the NEPAD Heads of State and Government Orientation Committee of January 2015 Decision {Assembly/AU/Dec.563(XXIV) Para 11} as

[21] United Nations Guidelines for consumer Protection (as expanded in 1999)

part of the implementation of the African Medicines Regulatory Harmonization (AMRH) Initiative.[22]

Treaty for the establishment of the African medicines agency

The commitment made by the African Ministers of Health during their First meeting held on 17 April 2014 in Luanda, Angola, jointly organized by the African Union Commission and World Health organization (WHO) to prioritize investment in regulatory capacity development; to pursue efforts towards convergence and harmonization of medical products regulation in RECs; to allocate adequate resources for the establishment of the African Medicines Agency (AMA), and the subsequent endorsement of the establishment of the AMA Task Team to spearhead the process.

The Parties undertake to accord to the AMA and all its personnel, its premises, property and assets, , and experts on mission providing advice or assistance to the AMA, the privileges and immunities as stipulated in the 1965 General Convention on Privileges and Immunities of the Organization of African Unity and the Additional Protocol to the OAU General Convention on Privileges and Immunities, and such facilities and courtesies as are necessary for the exercise of their functions in connection with the AMA[23]

Securing reliable, predictable and sustainable funding is one of the key agenda items within the Africa Union (AU) since its launch in 2001. At different moments, AU actors have expressed concern over the growing reliance on external partners to finance the continental integration and development agenda. The Constitutive Act2 of the AU promotes the self-reliance of the Union.[24] Similarly, Agenda 2063's aspiration number 7 wishes for Africa to become a strong, united and influential global player, and to be "fully capable and have the means to finance her development.[25] The Executive Council and the AU Assembly have taken various decisions on finding alternative sources of financing the Union. The Organization of African Unity (OAU) Heads of State and Government, during the 2001 Lusaka Summit5, authorized the Secretary-

[22] Treaty for the establishment of the African medicines agency
[23] Article 7 of Treaty for the establishment of the African medicines agency (AMA)
[24] Organization of African Unity, Constitutive Act of the African Union, 2000, Lome, Togo. Came into force on May 26, 2001
[25] African Union, Agenda 2063 Popular Version, 2013

General to undertake studies, with the assistance of experts, to identify alternative modalities of funding the activities and programs of the AU - bearing in mind that the Union cannot operate on the basis of assessed contributions from Member States only and to make appropriate recommendations. In addition,

in June 2006 the Executive Council adopted a Decision6 mandating the AU Commission (AUC) in consultation with member states to undertake further analytical work to evaluate the impact of the various funding proposals on various economies, particularly on national budgets, trade, investment (including legal implications of agreements) and business environment, and how they would provide sustainable revenue to the AU. More so, the AU Summit adopted the July 2007 Accra Declaration7 which called for the establishment of a Ministerial Committee to identify additional sources of financing the activities of the AU.

Resolutions of the pan African forum on consumer protection

From 21 to 23 July 2015, was held in N'djamena, Republic of Chad, the Pan-African Forum on Consumer Protection, on the initiative of the Association for the Defense of Consumer Rights (ADC Chad), in partnership with the international Scientific Committee of the Forum. Between 60 and 90% of citizen-consumers in our countries do not have any coverage against health risks. In view of the failure of public service to provide coverage against health risks for the majority of African citizens despite the centrality of health in development policies, African Heads of States and Governments at the AU Summit in Abuja in 2001 committed to invest 15% of their national budgets in health. Very few have achieved this at the deadline set in 2015.

In view of the challenges outlined above, the participants to the Forum have resolved to conduct national and regional campaigns to call on African decision makers to establish and implement transparent policies that promote equity and equality of citizens in access to such essential basic services like energy and health at national and regional level. Call on our decision makers to invest in the diversification and sustainability of energy sources to reduce our dependence on fossil fuels, express our appreciation and support the African States that have introduced policies such as the Universal health coverage and call on other countries to follow suit in order to facilitate citizens' access to essential health services.

The continental and Pan-African framework for consultation and action for consumer protection.

The African Union space which gathers today more than one billion consumers, and in 2020, is today a significant economic issue. The economic integration underway in different sub regions of the continent and at continental level will result in opening borders, causing rapid flow of consumption products within the continent. This African integration will necessarily induce a consumer community submitted to the same rules and the same civic contributions[26].

Promoting horizontal cooperation between Consumers organizations in Africa in monitoring circulation of consumer products; supporting implementation of regional integration policies through intergovernmental institutions such as the African Union. Working for the Union of all African consumer organizations in order to boost the welfare of consumers in the Continent at this time of globalization. Regularly paying membership fees and annual fees.

2.3 East African community on protection of consumers of pharmaceutical products

The east African community competition act, 2006

An undertaking holding a dominant position in the relevant market shall no (a) directly or indirectly impose unfairly high selling or unfairly low purchasing prices or other unfair trading conditions (b)limit production or technical development and innovation to the prejudice of consumers; (c)discriminate between consumers or suppliers according to non-commercial criteria such as nationality or residence. (2)Subsection (1) shall apply to any undertaking on which small or medium sized undertakings are dependent (3) Any person who contravenes the provisions of this section commits an offence.[27]

The Kenya Information and Communications (Consumer Protection) Regulations, 2010[28] articulate a framework to uphold consumer rights and entitlements in the ICT sector. This framework will be complemented by the proposed Consumer Protection Bill, 2011 that seeks to provide for a consolidated regulatory platform for consumer protection for all goods and services

[26] Resolutions of the pan African forum on consumer protection
[27] The east African community competition act, 2006, Part III section 1-3
[28] S. 3(1) and (2) of the Regulations provide for the rights and obligations of customers of ICT licensees

consumed in Kenya.[29]The Bill lists as its objects, the protection of the consumer and prevention of unfair trade practices in consumer transactions.

Part IV of the proposed law articulates rights and obligations related to specific consumer agreements, and goes on to recognize Internet agreements. This recognizes that while conventional transactions were entered into in the physical space, increasingly the novelty of agreements in the digital space continues to pose consumer protection challenges in Kenya. The memorandum of objects and reasons notes that it is a particular source of concern that no law currently exists to specifically regulate consumer agreements entered into online and that the proposed legislation aims to extend protection to consumers doing business via the Internet.[30]The Bill awaits its second reading in Parliament.

[29] http://www.kenyalaw.org/klr/index.php?id=98. The text of the Bill is available at number 51 Bill Tracker, 2011

[30] Internet agreement" means a consumer agreement formed by text-based Internet communications.

CHAPTER THREE
LEGAL AND INSTITUTIONAL FRAMEWORK ON CONSUMER PROTECTION OF PHARMACEUTICAL PRODUCTS IN UGANDA

3.0 Introduction

This chapter provides an assessment of the legal and institutional framework on consumer protection of pharmaceutical products in Uganda. The focus of this chapter provides an assessment of the status of the legal systems and provides the mechanisms for the assessment of the existing legal system.

3.1 Legal framework on consumer protection of pharmaceutical products

National Drug policy

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

The National Drug Authority Act (the Act) is the main law governing medicines regulation, but its scope is limited to "drugs". An amendment is in process to add medical devices, cosmetics, food safety, medical laboratory reagents, products for diagnosis, surgical supplies, blood, public health products and other products that are typically found in health systems as these too are often falsified or substandard and require regulatory oversight

The Act is accompanied by a set of nine regulations, all dated March 2014, dated after the Act and covering essential topics of Licensing, the suitability of premises, ectoparaciticides, field trials, conduct of clinical trials, control of publication, and Advertisement, Fees, Pharmacovigilance, importation and Exportation and Drug Registration. Regulatory inspectors, customs and border patrol and law enforcement officials are often not adequately equipped or authorized to identify FS medicines, properly prepare a file for prosecution, take immediate actions such as a preliminary seizure, and proceed through to conviction and sentencing. Law cannot implement itself and there must be adequate numbers of skilled staff to conduct the regulatory functions.

Pharmacy and Drug Act Chapter 280 of 1970

Pharmacists are regulated by the Pharmacy and Drug Act Chapter 280 of 1970 and the Standards of Pharmacy Practice of 2001. Pharmacists and pharmacies cannot be treated separately in this report as the regulatory requirements are inseparable a pharmacist is essential to obtaining a license to open a pharmacy[31]. Informants stated that the requirements are the same for private and public sector pharmacies and this would be the case if the pharmacy were in a public or private hospital or clinic or a stand-alone outlet. Pharmacists are also required on site for wholesale businesses

National Health Policy

The National Health Policy (2009) recognizes that adequate quantities of affordable, good quality essential medicines and health supplies should be accessible to all who need them. As a policy, the government undertakes to ensure availability and affordability of safe, good quality medicines and health supplies to the population of Uganda.

The policy however, also acknowledges that the public sector has been unable to fulfill its mandate to provide medicines to those who need it because of inadequate financial and human resources, capital investment and related management issues. The policy cites, as part of the explanation, shortfalls in the regulatory framework, and highlights the Pharmacy Profession and Practice Bill; Uganda Medicines Control Authority Bill; National Health Insurance Bill, and the Traditional and Complimentary regulatory Bill as some of the laws that are pending enactment/review to fill the gap. In the policy, government pledges to encourage local production of medicines and ensure compliance with Standards of Good Manufacturing Practices[32].

Uganda Health Sector Strategic and Investment Plan

The Uganda Health Sector Strategic Investment Plan (2010/11-2014/15) identifies the major stakeholders involved in national medicines as National Medical Stores, Joint Medical Stores, and NDA. As a strategy to increase the supply of medicines and essential health services, the plan undertakes to strengthen the policy and legal environmental governing the production,

[31] Pharmacy and Drug Act Chapter 280 of 1970, article 12;1-4
[32] moH, (2010), National pharmaceutical sector strategic plan (NPSSP ii) 2009/10-2013/14

procurement and distribution of pharmaceuticals in Uganda. To this end the plan undertakes to work with local companies and encourage them to produce medicines local in compliance with Standards of Current Good Manufacturing Practices (MoH, 2010),

Food and Drugs Act

The Food and Drugs Act, which has been in effect since 1959, provides for the prevention of adulteration of food and drugs and related matters. The Act makes it an offence to add any substance to, or abstract any constituent from, a drug so as to affect injuriously the quality, constitution or potency of the drug, with intent that the drug shall be sold in that state. It is also an offence to sell any drug which is not of the nature, or not of the substance, or not of the quality, of the food or drug demanded by the purchaser

3.2 Institutional framework

Ministry of Health

The Ministry of Health (MoH) is the lead authority for the health sector. It is responsible for "national planning and policy formulation, setting standards and guidelines, capacity building, training, monitoring and evaluation, provision of technical support and mobilization for the health sector.[33] The Ministry of Health is led by three cabinet members: a Minister of Health and two State Ministers of Health (State Minister of Health for General Duties and State Minister of Health for Primary Care).

National Drug Authority

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.[34] Hence,

[33] A bill is pending to amend the Act that has been in process for some time. A copy was unavailable during the mission as it is in draft. See the NDA Official website: http://www.nda.or.ug/ (last accessed 31 August 2015).
[34] Ministry of Health, Draft Pharmaceutical Sector Policy Report, 2013.

pharmacovigilance 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 finalized with an expanded mandate for NDA.

Licensure

In Uganda the NDA Act only requires pharmacies and drug sellers (drug shops) (Art. 14, 15) and wholesalers (Art. 37) to be licensed. A Licensing Regulation requires manufacturers to be licensed, although this regulation has questionable enforceability. Actors such as transport operators are not required to be licensed. The Act only requires a premises such as a storage facility to be certified as to suitability[35], and this certificate is tagged by the NDA to a licensed company. The Act also requires an import or export to be authorized by a permit (Art. 44, 45).

Although there may be some aspect of Ugandan law that differs, in general a regulation such as the Licensing Regulation is insufficient to legally mandate manufacturers to be licensed operators if there is nothing in the legislation. This is especially important as wholesalers, manufacturers, importers and exporters, transport and storage operators are private sector actors who function under corporate umbrellas. Thus the law must act against the regulated actor for it to have optimal effectiveness. For many reasons this patchwork of licensure requirements should be harmonized and as is likely the case, must be corrected with an amended law and not another regulation.

Inspection

NDA inspectors are authorized by Part VII, Article 50 of the Act to enter and investigate, at all reasonable times, any premises for which a certificate of suitability has been issued, any premises, vessel or vehicle if the inspector has reasonable cause to suspect an offense under the Act has been or is being committed, or any premises where narcotic drugs are being manufactured or supplied. In effect inspectors are granted wide scope to enter and inspect any actor or location where medicines may be located or be in production, on sale, under transport, or in storage. Once an inspector enters or investigates, he or she may inspect, require persons to

[35] Art 17 of the National Drug authority act of Uganda.

furnish information as to the activities conducted there or in the vehicle or vessel, and to take away any drug or records or documents found (Art. 51).

National Medical Stores

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 organization, 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 subsidized 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 harmonized 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.[36]

Pharmacy council

The Pharmacy Council is the governing body of the Pharmaceutical Society, which was created under the Pharmacy and Drug Act. This Act contains a number of provisions important to managing the problem of FS medicines and requiring pharmacists to: keep records of sales and storage conditions, obtain product only through an authorized source of supply, appropriately

[36] MOH, Health Facility Storage Assessment Report, 2012/13

store products, report suspected defective or counterfeit medicines, comply with recall warnings, comply with GMP if the pharmacist works for a manufacturer, sell to licensed outlets and keep records on sales only if the pharmacist works in wholesale and distribution (not defined), follow standards for disposal of unwanted and expired drugs, and ensure the Chief Inspector of Drugs witnesses destruction of such drugs.

The on-site pharmacist is personally required by his or her license to comply with the Pharmacy Standards of Practice that include GMP (though not Good Distribution Practices (GDP)). Failure to do so may result in disciplinary proceedings that could result in license revocation or suspension. However, a pharmacist whether in a manufacturing facility or retailer or wholesaler is only required to be on site 40% of the time according to the Standards of Practice but not the law. Therefore there is ample opportunity for unsupervised activity and activity that falls outside the scope of any good practices. This may account for some of the substandard medicines in circulation.

As with any such requirement, there must be periodic inspection with sufficient frequency and in accordance with risk based inspection procedures to confirm compliance. For cases of non-compliance a procedure must be in place to impose consequences. The Pharmacy Council has prescribed such a procedure, and set of penalties that it can impose on the pharmacist. It is not clear that the Council or the NDA inspectors are sufficiently monitoring compliance across the country for these measures to have the intended effect.

Customs Department Uganda Revenue Authority

The Customs Department is administered by the Uganda Revenue Authority (URA). The priorities for Customs are related to fiscal matters. Though drugs are not taxed at entry into the country, import permits are routinely checked by Customs. The Customs Department has a list of prohibited items which cannot enter the country, among which are 'counterfeit items' (including medicines). Customs officials most commonly conduct random checks as they lack the technical capacity to determine whether the imported medicines are falsified or substandard. Customs informally reports that a few interventions have taken place such as operations in the Eastern Region, where the Customs Department has created rapid response units.

The URA provides the NDA and other agencies at the borders access to the URA information system, including information on consignments entering the country. Imports need to be cleared by all agencies prior to entering the country. The NDA and Customs have joint offices at some border crossings, e.g. at the Malaba border with Kenya. The Eastern border is the most porous. There are four Customs stations along this border, but there are many more roads that cross the country. There is only one international airport in Uganda, where the NDA inspects drugs imports. Informants suggested an approach to solve this issue is to form a task force on medicines, to aggregate data to indicate countries of origin known to be exporters of falsified and substandard medicines so as to profile flights arriving from countries on the list.

Directorate of Public Prosecutions

The Directorate of Public Prosecutions is established by the Constitution and is responsible for criminal prosecutions, including crimes related to falsified and substandard medicines. The NDA has held training workshops in which prosecutors have participated, either as participants or as trainers for inspectors on the prosecution of relevant crimes and offenses. Falsified medicines are found with both falsified packaging as well as with falsified or substandard content.

Inspectorate of Government

The Inspectorate of Government (IG) was initially established by the Inspector General of Government (IGG) statute in 1988. The Inspectorate of Government is now established by chapter 13 of the Uganda Constitution, which prescribes its mandate, functions and powers and other relevant matters. The Inspectorate of Government is an independent institution charged with the responsibility of eliminating corruption, abuse of authority and of public office. The powers enshrined in the Constitution and Inspectorate of Government Act include to; investigate or cause investigation, arrest or cause arrest, prosecute or cause prosecution, make orders and give directions during investigations; access and search enter and inspect premises or property or search a person or bank account or safe deposit box among others. The Inspectorate of Government has the mandate to oversee the work of the specialized agencies, including the National Drug Authority. to make sure that the public service is rendered in a proper and effective way.[37]

[37] The UNICRI study, "Confiscation of the Proceeds of Crime: a Modern Tool for Deterring Counterfeiting and Piracy" might serve as guidance to explore how sound legislation on confiscation of proceeds of crime and asset

CHAPTER FOUR

PRESENTATION AND INTERPRETTION OF INFORMATION

4.0 Introduction

This chapter is concerned with presentation and interpretation of findings for the study based on the constitutional review of documents presented on the legal, constitution and relevant acts related to laws and practice on protection of consumers of pharmaceutical products in Uganda. The presentation is based on the research objectives set in chapter one. The presentation is a secondary data review of the constitutional provisions including the aspects sought for in the study in line with the research objectives.

4.1 Legal provisions on consumer protection of pharmaceutical products in Uganda

A reasonable legislative and regulatory framework is in place but the law establishing NDA is being reviewed and the revised law is expected to further strengthen the regulatory framework and also expand the regulatory body's mandate. National Drug Authority has since inception placed a lot of legislative and regulatory emphasis on the private sector. However, since 2013, the NDA with support from development partners, initiated inspections of public sector health facilities for compliance with Good Pharmacy Practice (GPP) standards. By mid-2014 about 30 percent of public and PNFP health facilities had been inspected, with 18% (of those inspected), 18 percent had been certified for Good Pharmacy Practice[38]. The quality of pharmaceutical products imported into the country has significantly improved as evidenced by the drop in products failing quality tests from 11 percent in 2010/11 to 4 percent in 2013/14. Steps being made within the East African Community (EAC) and at the Africa level towards regional regulatory harmonization are further expected to improve the quality of medicines circulating in the country. NDA has reported an increase in the number of cases of adverse drug reactions from 268 in 2010/11 to 396 in 2011/12[39]. However, pharmacovigilance activities are still not well implemented across the country.

The NDP guides the import, production, distribution, marketing, export, and use of pharmaceuticals in the public as well as the private sectors in Uganda. It aims to ensure the

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recovery can serve as an effective tool in counterfeiting cases. Available at: http://www.unicri.it/news/article/2013-04-25_Proceeds_of_Crime_Legislation (accessed May 2018).

[38] See http://apps.who.int/gb/ssffc/e/a_msm1.html

[39] MoH 2013. Draft Pharmaceutical Sector Policy Report.

availability, accessibility, and affordability at all times of essential medicines of appropriate quality, safety and efficacy, and also promotes their rational use.

Published in 2002, the NDP provides a policy framework for local manufacturing of medicines. The policy's goal is "to consider, and support, if appropriate, development of efficient local production of essential drugs of good quality, safety and efficacy, relevant to national needs and resources (MoH, 2002). This is in line with government efforts to ensure reliable provision of the National Minimum Healthcare Package. In order to create an environment conducive to increased national capacity for the production of essential medicines and to ensure that local production meets current Good manufacturing Practices (cGMP) requirements, the NDP outlines the following key strategies[40].

The national drug authority provides an overview of the general situation of the assessment of the authority and overseeing that the products are of high quality, systematic inspection of premises and processes to ensure full adherence to licensing requirements; creation of a monitoring system and mechanism for support supervision to ensure maintenance of required standards. The improving local pharmaceutical technical capacity by encouraging and assisting in the training of sufficient numbers of staff in pharmaceutical production techniques, quality assurance. There has been progress in the implementation of the NDP strategies. For example, the pharmaceutical section of the Ministry of health has provided scholarships for pharmacists involved in the local production of medicines.

The Ministry of health does not control the incentive regime which has the potential to be a major force behind increased local pharmaceutical production. It can only recommend and offer technical briefings. This is because the incentives for local investors are controlled and implemented by the Uganda Investment Authority (UIA). Interviews have revealed that local manufacturers have to lobby for incentives on their own, often with only limited success

The national health policy acknowledges that the public sector has been unable to fulfill its mandate to provide medicines to those who need it because of inadequate financial and human

[40] Connie Lau, Presentation to International Forum on Justice and Consumer Rights, UNGCP, Wuhan, China 2013.

resources, capital investment and related management issues. The policy cites, as part of the explanation, shortfalls in the regulatory framework, and highlights the Pharmacy Profession and Practice Bill; Uganda Medicines Control Authority Bill; National Health Insurance Bill, and the Traditional and Complimentary regulatory Bill as some of the laws that are pending enactment/review to fill the gap. The policy is however silent on the consumer protection on pharmaceutical products given that the most environments that exist does not provide an adequate regulation for the pharmaceutical products though focus on ensuring healthy products provision to the people.

The National Drug Authority Act is the main law governing medicines regulation, but its scope is limited to "drugs". An amendment is in process to add medical devices, cosmetics, food safety, medical laboratory reagents, products for diagnosis, surgical supplies, blood, public health products and other products that are typically found in health systems as these too are often falsified or substandard and require regulatory oversight[41]. This act with the capacity of the authority undertakes licensing, testing and checking of the pharmaceutical products to ensure compliance to quality and enhancing the mechanisms. The act is however limited in scope as products that are found consumer unfriendly can be impounded but not destroyed, these therefore limit the scope of the operation of the authority[42].

The Food and Drugs Act, which has been in effect since 1959, provides for the prevention of adulteration of food and drugs and related matters. The Act makes it an offence to add any substance to, or abstract any constituent from, a drug so as to affect injuriously the quality, constitution or potency of the drug, with intent that the drug shall be sold in that state.[43]The presence of this legal provisions does not have an adequate supporting legal or legislative framework that support the implementation of the laws concerning the food and drugs in the environment necessary for enhancing the provision of food items in a highly competitive environment.

[41] National Drug authority act, Uganda
[42] Art. 30(a)) prohibits the sale of any substandard 'drug, medical appliance or similar article.' This is the only reference in the Act to other health products.
[43] The Food and Drugs Act, 1959

manual containing the requirements for reporting, storage, track and trace, among others and condition the license on their compliance[52].

The Ugandan NDA is not obligated by its enabling law to conduct investigations on receipt of a safety signal or take further actions. It may do so according to Articles 5 and 8 of the Pharmacovigilance Regulation. It is obligated however to control the quality of drugs, by Article 5 of the Act but the Regulation limits the obligation. A stronger, clearer statement on the elements or activities of control could be helpful in the new law if and when amended and may provide a basis to seek additional resources to carry out the mandate.

The Act is deficient in that it only authorizes the taking of a drug, record or other documents but not labeling or packaging materials or finished ones, materials or production equipment. Falsified drugs are often, but not always, rudimentary, but as technical testing equipment is not generally used during inspections, a drug sample must be sent to a laboratory for analysis. This can delay regulator action and allow a wrong doer to hide evidence or leave the jurisdiction. Moreover, the laboratory only analyses composition, but does not trace for the source of the products. It is common to detect products with both falsified labels and contents. Moreover since Ugandan law does not have a pedigree[53] requirement or track and trace requirement36, the documents that might be available may not lead to useful information on the source of finished medicines or recipients, packaging or labeling or equipment.

The Act provides inspectors the right to 'take away" drugs, records or documents, but not the right to impound suspicious items where they are found (Art. 51)[54].This means that the NDA has to immediately remove suspicious products, which may be in large quantities. This gap in the seizure authorization has caused NDA problems in the past and must be filled by legislation to authorize the best and most efficient means to hold the goods and other items pending testing.

[52] Legal requirements related to the European Medicines Agency (EMA) pharmacovigilance system for human medicines are laid down
in Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) No 520/2012.
[53] https://www.gov.uk/government/world-location-news/international- anti-corruption-day-uk-working-with-uganda, andhttps://www.gov.uk/government/world-location-news/international-anti-corruption-day-uk-working-with-uganda (accessed 30 May 2018).
[54] Uganda National Drug act. Article 51

These powers include the facility closure, suspension of license, padlocking the door, posting a guard, and the right of seizure must be extended to the materials and equipment of production and those for packaging, labeling and other items used in relation to medicines. To ensure the good governance of such a procedure, a process to present the findings to a board or court for an order permitting final seizure and destruction should be included in an amended or new law.

Once the status of medicine is confirmed, the next phase is to permanently remove the items from the market, or to 'take away' in the language of the Act. Following seizure, the next step is to dispose or destroy according to national and international guidelines for the hazardous or medical waste, after the conclusion of court proceedings. The Act does not authorize the NDA to destroy or dispose of FS medicines once confirmed. This authority, since it has an effect on title to goods, must be in the law otherwise there is a risk of claim of conversion, as has happened in Uganda. This process must also be done according to procedures that demonstrate good governance and rule of law. This means there is an opportunity to present the case to a board or court and for the owner of the products to defend after which the board or court will make a determination[55].

4.4 Recommendations on how the challenges of consumer protection can be dealt with

Relevant civil society organizations include patients and consumer groups, advocacy organizations, and independent professional associations of medical practitioners and pharmacists. There is a need for all stakeholders to shift from the perception of civil society as simply consumers of medicines to the engagement of civil society as full partners in the national response to FS medicines.[56] This reflects the human rights-based approach to health and development, which emphasizes participation, accountability, equality and nondiscrimination. This is particularly important as some communities still misunderstand the role of the National Drug Authority (NDA) and the importance of addressing FS medicines in Uganda. This misunderstanding has led to a lack of cooperation with government authorities in regulating FS medicines, and even hostility towards government inspectors responding to FS medicines. The general public needs to be empowered and provided with the information necessary to create the

[55] Ministry of Health-Republic of Uganda: Essential Medicines and Health Supplies List for Uganda (EMHSLU) 2012. Kampala; 2012

[56] Sylvester Rugumambaju and Paul Kutyabami. 2010. Pharmaceutical Sector Profile: Uganda. United Nations Industrial Development Organisation (UNIDO), Vienna

demand for appropriate, quality medicines. This includes for example ensuring that drugs are appropriately labelled, and expiry dates are checked[57].

Uganda has a vibrant and independent civil society sector, and there are several strong national civil society organizations which include health in their mandates[58]. The role of faith-based communities and traditional leaders should also be considered. Civil society organizations should be engaged at all levels in the national response including through representative participation in national structures. Trusted civil society champions and leaders should also be engaged in public education campaigns to inform people about the dangers of FS medicines. Finally, civil society engagement should be supported to extend to include regional and international collaboration regarding FS medicines[59].

There is a need to include a clear definition of FS medicines that is consistent throughout the legal system. Currently there is no definition of 'counterfeit' in the Act, though Art.[60] Refer to impure drugs. The Regulation on Pharmacovigilance (PMV Regulation) defines "counterfeit drug" to mean "a drug which is deliberately or fraudulently mislabeled with respect to its identity, content or source." A full definition of medicines could include elements that distinguish accidental substandard, negligent substandard and intentional substandard, or accidental false label or packaging, as compared to intentional falsification (such as changing expiration dates).

The NDA must build a sufficient inspectorate to comprehensively cover the entire country and all its actors. The inspectors must be sufficiently trained and knowledgeable on how to conduct a proper inspection and what to look for in terms of compliance or lack thereof. The budget must be adequate to hire a sufficient number of inspectors who are trained on the requirements and their verification and what to do in case of a suspected wrong medicine. Improve the capacity of the laboratory system, in terms of the numbers of labs, the speed at which tests are completed

[57] Consumers International: Model Law for Consumer Protection in Africa, 1996. Also: A Guide to Developing Consumer Protection Law, 2011.
[58] WHO Rapid Alert System for combating counterfeit medicine
[59] Consumers International, Guidelines for Consumer Policy in Central and Eastern Europe, 2000
[60] WHO Good Distribution Practices for Pharmaceutical Products. WHO Technical Report Series, No 957, 2010, Annex 5. Available at http://apps.who.int/medicinedocs/en/d/Js18678en/ (accessed 2 June 2018).

and increasing the complexity of tests that can be conducted to determine if a product is substandard. Expand field testing of medicines though rapid tests bar coding and use of mobile technologies to verify medicines[61].

Creating an integrated reporting and complaint mechanisms, with NDA as focal point (using various tools, e.g. apps and electronic platforms), including a toll free telephone hotline reporting and for answering to questions on FS medicines. Build an electronic platform for information sharing across agencies with a section dedicated to exchange of case law and best practices (possibly NDA can be the focal point). Establish a specialized task forces comprised of the NDA, MOH and Customs among others and create a Joint Investigation Team, to track countries of origin of FS medicines to improve surveillance at border crossings, and to finalize develop and implement a national strategy to combat FS medicines. Create coordination between the MOH and NDA to ensure that all actors in the system are in compliance. Harmonize operating requirements for public and private pharmaceutical actors, and private and hospital pharmacies and coordinate inspections with the NDA to ensure all pharmaceutical activities are correct[62].

Create an internal review board Uganda lacks an internal review board which the NDA should establish and operate either alone or in conjunction with the ministry of health. It can hear cases of suspected FS medicines, issue orders for final seizure and destruction, determine if the inspector is correct in observing non-compliance and sanction with license suspension or revocation for non-compliance.

Regarding licensing, Review the licensing requirements and aligned these in the law and regulation so that all actors in the supply chain are required to be licensed including wholesalers, retailers, transporters, warehouseman, manufacturers, importers and exporters. The definitions in Articles 14 and 15 require revision so that there is internal consistency with the PMV regulations and all licensed actors and that the powers of inspection are clearly applicable to any and all actors in the legal and illegal supply chain. It is also important to clarify the distinction between

[61] Government of Uganda, Ministry of Health (2008), National Pharmaceutical Sector Strategic Plan for Uganda (NPSSP) II 2009/10-2013/14

[62] M. Roy, J. Marchetti, H. Lim, Service Liberalization in the New Generation of Preferential Trade Agreements. How Much Further Than GATS? WTO Economic Research and Statistics Division, ERSD 2006-7.

retails sales and wholesale activity, so that wholesalers cannot sell drugs to unlicensed persons (i.e. drug shops) and that their record keeping is extended beyond the immediate source of their supply. All actors must have a clear set of guidelines for their activities such as GDP. A realignment of the standards and scope of practice for all actors in the supply chain will be helpful to clarify gaps and ensure that a comprehensive set of standards are applicable to the relevant actors[63].

NDA has the mandate to undertake inspection, approval, verification and approval of local manufacturers of pharmaceutical products, to guarantee that the quality of medicines on the market from both local and foreign producers. The process of inspection and approval should be streamlined to fast-track the process through which pharmaceutical products can be authorised for marketing while also ensuring that the review is robust enough to guarantee quality. This is necessary to encourage the local manufacturers to lay out new lines of medicines and this encourages R&D into new medicines. Also the regional level, harmonization of regulation should improve inspection and market approvals in the regional market[64].

The Tax policy should also be streamlined to clarify on the items which are subject to tax exemptions. While the government has undertaken to waive taxes on machinery and equipment necessary to set up manufacturing plants in all phases, the scope of these waivers has not been properly defined and some manufacturers have had to pay taxes on accessories, packaging material, and spare parts of equipment and air-handling systems which are essential to the running of pharmaceutical plants. It is therefore important that the local policy in relation to subsidies and incentives is clearly defined by the government and this could be through the commissioning of a comprehensive guidelines tool on the incentives available to local manufacturers and on what they are available for.

[63] See: http://www.greatplacetowork.com.pe/storage/documents/suplemento-gptwperu-2014baja.pdf, page 9.
[64] WHO (2010). The World Health Organization Report 2010-The Uganda Pharmaceutical Sector Scan. Part 1 of Component 1 of MeTA Baseline Assessment, June 2010. Geneva.

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

This chapter is concerned with the summary of the findings, conclusions and recommendations of the study.

5.1 Summary of the findings

The appraisal of the existing legal framework governing the consumer protection of pharmaceutical products in Uganda. The composition of this chapter is governed by the following provisions undertaken in the study. The summary is therefore provided here under as provided below.

5.1.1 Legal provisions on consumer protection of pharmaceutical products in Uganda

The national drug authority provides an overview of the general situation of the assessment of the authority and overseeing that the products are of high quality, systematic inspection of premises and processes to ensure full adherence to licensing requirements; creation of a monitoring system and mechanism for support supervision to ensure maintenance of required standards. Published in 2002, the NDP provides a policy framework for local manufacturing of medicines. The policy's goal is "to consider, and support, if appropriate, development of efficient local production of essential drugs of good quality, safety and efficacy, relevant to national needs and resources.

The national health policy acknowledges that the public sector has been unable to fulfill its mandate to provide medicines to those who need it because of inadequate financial and human resources, capital investment and related management issues. The provisions of the national drug authority act provides that the understanding of the fact that despite the provisions of the article, the article is relevant in the provisions for assessment and not capable for managing the consumer protection as the provisions are limited in scope.

5.1.2 Effect of contributions of the Food and Drugs Act and National drug policy and Authority Act, Cap. 206 on consumer protection of pharmaceutical products.

The food and drugs act and the national drug policy provides for an establishment of an act to establish a national drug policy and a national drug authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda The Drug Inspectorate Services Department of NDA is responsible for the inspection of pharmaceutical manufacturers (local and foreign) and distributors (pharmacies, chemist shops, health units, and hospital dispensaries. The drug assessment and registration department of NDA is responsible for assessing, registering and maintaining a register of all medicines in Uganda

NDA's mandate, which requires that the Ugandan public has access to accurate, reliable, objective and non promotional information on medicines and health supplies. To meet this objective, the department provides guidelines for and screens advertisements, vets medical/marketing representatives, conducts post marketing studies, surveillance and dissemination of the information obtained.

5.1.3 Legal challenges to consumer institutional framework on protection of pharmaceutical products in Uganda

Regulatory inspectors, customs and border patrol and law enforcement officials are often not adequately equipped or authorized to identify Falsified and substandard medicines (FS) medicines, properly prepare a file for prosecution, take immediate actions such as a preliminary seizure, and proceed through to conviction and sentencing.

The ability of the National drug authority is to prevent, detect and respond to FS medicines is hampered by the lack of reporting by pharmacists and health professionals, who are required to report adverse drug reactions and about spoilt medicines. These reports are critical to informing the post market surveillance system, however at present some stakeholders are not obligated to do so by law.

5.1.4Recommendations on how the challenges of consumer protection can be dealt with

With the weaknesses in consumer protection by the relevant institutions and legal framework , The NDA must build a sufficient inspectorate to comprehensively cover the entire country and all its actors. The inspectors must be sufficiently trained and knowledgeable on how to conduct a proper inspection and what to look for in terms of compliance or lack thereof. Create an internal review board Uganda lacks an internal review board which the NDA should establish and operate either alone or in conjunction with the ministry of health. Regarding licensing, Review the licensing requirements and aligned these in the law and regulation so that all actors in the supply chain are required to be licensed including wholesalers, retailers, transporters, warehouseman, manufacturers, importers and exporters.

5.2 Conclusions

The study set to examine the existing laws and practice on protection of consumers of pharmaceutical products in Uganda. The objectives were to examine the legal provisions on consumer protection of pharmaceutical products in Uganda. To explore the effect of contributions of the Food and Drugs Act and National drug policy and Authority Act, Cap. 206 on consumer protection of pharmaceutical products and to establish the legal challenges to consumer institutional framework on protection of pharmaceutical products in Uganda and finally to make recommendations on how the challenges of consumer protection can be dealt with. The study provided and concludes that the legal framework on protection of consumers on pharmaceutical products is much vested in the national drug authority and act that provides for the insurance that the products are in good conditions for the customers. The second objective reveal that the food and drug authority act has had an effect on ensuring consumer protection thought the protections is limited due to low effectiveness of the law and the act that hinder the management of the country. On the third objective, the National drug authority is to prevent, detect and respond to spoilt medicines is hampered by the lack of reporting by pharmacists and health professionals, who are required to report adverse drug reactions and about spoilt medicines, the authorities are however being hampered by the existence of a sound legal systems. However there is need for the recommendations in undertaking the mechanisms for improving consumer protection of the pharmaceutical products.

5.3 Recommendations

The legal framework on the consumer protection is inadequate; there is need for the authority to enhance the management of the business and organizations. Therefore the mandate of the national drug authority needs to be enhanced to enable confiscation and handling of the provisions under the legal the environment.

For any regulator and particularly for resource constrained environments adopting the choice with the least amount of associated work may be desirable, but not necessarily the best in the long run. A regulation is clearly fast to finalize than legislation as it can be implemented within the regulatory agency without approval from Parliament. Some regulatory options require a law; an existing law, an amendment to existing law or an entirely new law. The Law is required when a right is granted or limited or a duty or responsibility imposed on any actor or the regulator.

Establish a specialized task forces comprised of the NDA, Ministry of Health and Customs among others and create a Joint Investigation Team, to track countries of origin of spoilt medicines to improve surveillance at border crossings, and to finalize develop and implement a national strategy for improving the management of pharmaceutical products for ensuring consumer protections.

There is need for amendment of the act of NDA to enable them in enhancing the management of the pharmaceutical drugs, enhancing the mandate and increasing the responsibility coverage by the authority through the law to enable the authority in impounding, confiscation and management of the environment for the pharmaceutical products.

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