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THE REGULATION OF SEX LUBRICANTS FOR SAFETY IN KENYA

BY

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I, Mercy Mutindi Muema do hereby declare that this LLM Research Project Paper is my original work. It has not been submitted for award of any degree or any other academic credit in any other University or learning institution. I also declare that any reference made to books, texts, articles, journal articles, papers, websites and journals, and any other pertinent materials have been duly acknowledged.

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Dedication

I dedicate this thesis to God Almighty, Father, Son and Holy Spirit. My belief in You has been a constant source of inspiration throughout my academic journey and fueled my determination to reach this milestone. This thesis stands as a tribute to my journey of surrender, Your guidance and your enduring influence on my life and aspirations. May my work be pleasing and acceptable to You and may your children enjoy sex in true safety.

"See what great love the Father has lavished on us, that we should be called children of God! And that is what we are!" 1 John 3:1a (NIV)

List of Abbreviations and Acronyms

ACHPR	African Charter on Human and Peoples' Rights
AIDS	Acquired Immune Deficiency Syndrome
AU	African Union
AUC	African Union Commission
BV	Bacterial Vaginosis
CEDAW	Convention on the Elimination of all Discrimination Against Women
COFEK	Consumer Federation of Kenya
CRPD	Convention on the Rights of Persons with Disabilities
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
FHI360	Family Health International
HIV	Human Immunodeficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICPD	International Conference on Population and Development
ICPEN	International Consumer Protection and Enforcement Network
ICRH	International Center for Reproductive Health
IPR	Institute of Primate Research
ISO	International Organization for Standardization
ISSM	International Society for Sexual Medicine
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KENIA	Kenya National Innovation Agency
KNCHR	Kenya National Commission on Human Rights
MDGs	Millennium Development Goals
MoH	Ministry of Health
MSM	Men who have Sex with Men
NACOSTI	National Commission for Science, Technology & Innovation

NRF	National Research Fund
PMN	Premarket Notification
PPB	Pharmacy and Poisons Board
PVoC	Pre-Export Verification of Conformity
SDGs	Sustainable Development Goals
SRH	Sexual and Reproductive Health
SRHRs	Sexual and Reproductive Health Rights
STIs	Sexually Transmitted Infections
UHC	Universal Health Coverage
UN	United Nations
UNDHR	Universal Declaration of Human Rights
UNFPA	United Nations Population Fund
USA	United States of America
WHO	World Health Organization

List of Constitutions and Constitutional Instruments

Constitution of Kenya, 2010.

Constitution of Kenya, Act No. 5 of 1969.

Constitution of Nigeria, 1999

Constitution of the Republic of South Africa, 1996

List of Transnational Legal Instruments

African Charter on Human and Peoples' Rights (Banjul Charter), 1981.

Convention on the Elimination of all Discrimination Against Women, 1979.

Convention on the Rights of Persons with Disabilities, 2006.

International Covenant on Civil and Political Rights, 1966.

International Covenant on Economic, Social and Cultural Rights, 1966.

Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Maputo Protocol), 2003.

List of Kenyan Statutes

Access to Information Act, 2016.
Competition Act, 2010.
Consumer Protection Act, 2012.
Food, Drugs and Chemical Substances Act, Cap 254.
Health Act, 2017.
Kenya Medical Supplies Authority Act, 2013.
Pharmacy and Poisons Act, Cap 244.
Sale of Goods Act, Cap 31.
Science, Technology and Innovation Act, 2013.
Standards Act, Cap 496.

List of Repealed Statutes

Science and Technology Act, Cap 250 Laws of Kenya

List of Foreign Statutes

Federal Competition and Consumer Protection Act, 2018 of Nigeria
Food, Drug and Cosmetic Act, United States Code, Title 21
National Health Act, 2014 of Nigeria
National Health Act, 2003 of South Africa
Consumer Protection Act, 2008 of South Africa

List of Kenyan Bills

Kenya Food and Drugs Authority Bill, 2019.
Reproductive Healthcare Bill, 2019.
Standards Bill, 2019.

List of Kenyan Rules, Regulations, Guidelines and Administrative Procedures

Food, Drugs and Chemical Substances (General) Regulations, 1978.
Guidelines for Registration of Medical Devices including In-vitro Diagnostics, 2022.
Implementation Guidelines for the Kenya Quality Model for Health, 2011.

Kenya Health Sector Strategic and Investment Plan, July 2013 - June 2017.

Ministry of Medical Services Strategic Plan, 2008-2012.

National Reproductive Health Policy Enhancing Reproductive Health Status for all Kenyans, 2008-2010.

National Reproductive Health Policy, 2022-2032.

National Reproductive Health Strategy, 2009-2015.

National Reproductive Health Strategy, 2014-2018.

List of Foreign Rules, Regulations, Guidelines and Administrative Procedures

National Guidelines for the Management of Sexually Transmitted and Reproductive Tract Infections 2007 - The United Republic of Tanzania.

National Health Policy, 2016 – Nigeria.

National Health Policy and Strategy to Achieve Health for All Nigerians, 1988.

National Health Sector Reform Programme (2004-2007) – Nigeria.

National Strategic Health Development Plan (2010-2015) – Nigeria.

Revised National Health Policy, 2004 – Nigeria.

List of Cases, Situations, Major Events and Anecdotes

Tania Warchol (f/k/a Tania Racha) et al. v. Love Honey Inc Case No. 3:15-cv-00238 [2015] (US).

CHAPTER 1

THE REGULATION OF SEX LUBRICANTS FOR SAFETY IN KENYA

1.1 Background to the study on Regulating Sex Lubricants for Safety in Kenya

The overarching argument of this thesis is that regulation of sex lubricants in Kenya is critical in ensuring that the reproductive health rights and safety of users are safeguarded.

This thesis therefore explores and analyses the regulatory framework governing sex lubricants in Kenya, their limitations if any and determines whether they adequately provide for the reproductive health and safety of users of sex lubricants.

Sex lubricants are applied to the condom, vagina, penis or rectum to improve lubrication, moistening and comfort during intercourse.¹ Those pre-applied to the condom during manufacturing are referred to as condom lubricants while those packaged separately in bottles or tubes are referred to as personal or additional lubricants.² Those used for medical purposes are known as patient lubricants. Patient lubricants are used to lubricate a body orifice to facilitate the entry of a diagnostic or therapeutic device.³

This thesis only analyses the regulatory framework governing the regulation of condom and personal or additional lubricants and shall collectively refer to them as sex lubricants.

There are a variety of sex lubricants in the market based on the composition of ingredients used in making them. Categories include the widely used water based lubricants, silicone-based, petroleum-based and oil-based sex lubricants.⁴ In terms of use, particularly here in Kenya, sex lubricants are widely used by adults engaging in intercourse but more so by postmenopausal

¹ World Health Organization (2012) *Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360, Advisory note, Switzerland* at https://apps.who.int/iris/bitstream/handle/10665/76580/WHO_RHR_12.33_eng.pdf;jsessionid=ED748CBFD3DE69897893193C82780ACE?sequence=1 (accessed 13/05/2020).

² Lauren Harvey (2016) *Classification of Silicone-Based Personal and Condom Lubricants Using DART-TOFMS*, Masters Thesis, University of Central Florida.

³ Electronic Code of Federal Regulations (2020) "Title 21" at https://www.ecfr.gov/cgi-bin/text-idx?SID=9c83e44dfb9af1f37b84f82df08adfa7&mc=true&node=se21.8.880_16375&rgn=div8 (accessed 08/05/2020).

⁴ WHO, *op. cit.*, at 1.

women⁵, men who have sex with men or MSM and by sex workers.⁶ Most of the research relied on in this study focus on the use of sex lubricants by MSM and sex workers.

Use of condoms and sex lubricants by MSM and sex workers has been strongly associated with a reduction of HIV transmission among them.⁷ Water based lubricants are therefore commonly distributed by MSM prevention programmes as they are believed to be an essential safety provision that reduce tears or damage to the rectal area and to prevent condom breakage⁸. Sex lubricants are therefore integral in the sexual and reproductive healthcare of its users.

Sexual and reproductive health care is regarded as a human right in the Constitution of Kenya, 2010, in relevant statutes and policies as well as in various international and regional instruments to which Kenya is party.

Article 43 of the Constitution provides that every person has the right to the highest attainable standard of health which includes the right to healthcare services including reproductive healthcare.⁹ Additionally, Article 46 guarantees consumer rights to all. Consumer rights include the right to goods that are of reasonable quality, the right to information necessary to gain full benefit from goods and the right to compensation for injury resulting from the defects of the goods.¹⁰

Sex lubricants are devices that directly affect the sexual and reproductive health of its users. Lubricants that are of a lower quality can adversely affect the health of users therefore sex lubricants should be of a high quality that promotes the highest standard of health of its users as per the Constitution.

The Consumer Protection Act also requires that suppliers of goods should supply goods that are of a reasonably merchantable quality.¹¹ It also guarantees all the consumer rights specified

⁵ Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) “A Comparative Study of Smugel and KY Jelly Vaginal Lubricating Gels,” *Journal of Reproduction & Contraception*.

⁶ WHO, *op. cit.*, at 1.

⁷ WHO, *ibid*.

⁸ Scott Geibel (2012) “Same-sex sexual behavior of men in Kenya: Implications for HIV prevention, programs and policy,” *Facts, Views Vis Obygn* at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3987482/> (accessed 26/09/2020).

⁹ Constitution of Kenya 2010, article 43(1)(a).

¹⁰ Constitution of Kenya 2010, Article 46 (1)(a-d).

¹¹ Section 5 (1).

in Article 46 of the Constitution. This therefore can ensure that the consumers of sex lubricants acquire quality lubricants in the market. Furthermore, they can seek redress in court in case of any injury arising from the use of these devices.

A proposed Kenya Food and Drugs Authority Bill aims to establish the Kenya Food and Drugs Authority. Once enacted, the Bill mandates the Authority to provide the regulation and management of drugs, medical devices and other health technologies.¹² However, the Bill has faced some challenges with some stakeholders maintaining that legislation and regulations on the administration of food and drugs should be separated.¹³

Institutions such as the Kenya Bureau of Standards (KEBS) established by section 3 of the Standards Act have the mandate to promote standardization in industry and commerce and to assist in the production of quality goods.¹⁴ Furthermore, the Pharmacy and Poisons Board established by the Pharmacy and Poisons Act is responsible for the regulation of health products and technologies.¹⁵

Other statutes and policies in Kenya such as the Health Act, the Reproductive Healthcare Bill and a number of policies like the National Reproductive Health Policy,¹⁶ the National Reproductive Health Policy Enhancing Reproductive Health Status for all Kenyans 2008-2010 and the National Reproductive Health Strategy¹⁷ all recognize sexual and reproductive health care as an important facet of this nation. They place an obligation on the state to protect, respect and fulfill the sexual and reproductive health rights of Kenyans.¹⁸ These statutes, policies, regulations and guidelines shall be discussed in detail in Chapter 2 of this study.¹⁹

¹² The Kenya Food and Drugs Authority Bill, 2019.

¹³ Bernardine Mutanu (2020) "Food and drug agency will put lives at risk, say experts," *Daily Nation*, at <https://www.nation.co.ke/health/Food-and-drug-agency-puts-lives-at-risk--Players/3476990-5494506-oc98vv/index.html> (accessed 21/05/2020).

¹⁴ Standards Act, Cap 496 Laws of Kenya.

¹⁵ Pharmacy and Poisons Act, Cap 244 Laws of Kenya.

¹⁶ National Reproductive Health Policy of 2007, 9 at <http://csakenya.org/wp-content/uploads/2016/10/National-Reproductive-Health-Policy-booklet-2007.pdf> (accessed 13/05/2020).

¹⁷ National Reproductive Health Strategy 2014-2018, 12 at <http://origin.searo.who.int/maldives/mediacentre/nrhs-2014-2018.pdf> (accessed 13/05/2020).

¹⁸ Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

¹⁹ Cf Chapter 2 of this LLM Research Project Paper.

International legal instruments also acknowledge that the sexual rights of individuals are human rights and therefore safeguard their sexual and reproductive rights. Some of these international legal instruments include the Convention on the Elimination of all Discrimination Against Women (CEDAW)²⁰ and the African Charter on Human and Peoples' Rights (Banjul Charter).²¹ Sexual and reproductive health are also important in achieving the Sustainable Development Goals (SDGs) particularly goal 3 on good health and well-being.²² This goal seeks to ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes. Chapter 2 of this thesis will delve deeper and analyse the legal and regulatory framework nationally and internationally that provide for the safety of users of sex lubricants.

Sex lubricants are generally regarded as low-risk products and are subject to only limited regulatory controls.²³ In fact, their regulation in Kenya and many other developing countries is not explicit as the relevant legal authorities focus on the wider aim of ensuring safe and affordable reproductive healthcare services and devices.

Developing countries often rely on guidance from more stringent regulatory bodies such as the Food and Drug Administration (FDA) of the United States of America (USA) or the European Medicines Agency (EMA) in Europe.²⁴ This thesis therefore relies on the mentioned authorities as well as regulations from international organizations such as the World Health Organization (WHO) and the International Organization for Standardization (ISO) for guidance.

²⁰ Art 16 (1) (e).

²¹ Article 16.

²² United Nations (2021) "Sustainable development goals: Goal 3: Ensure healthy lives and promote well-being for all at all ages" at <https://www.un.org/sustainabledevelopment/health/> (accessed 20/10/2021).

²³ WHO (2012) *Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360, Advisory note, Switzerland* at https://apps.who.int/iris/bitstream/handle/10665/76580/WHO_RHR_12.33_eng.pdf;jsessionid=ED748CBFD3DE69897893193C82780ACE?sequence=1 (accessed 13/05/2020).

²⁴ Scott Geibel (2013) "Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa," *Journal of the International AIDS Society* 2-3 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3708353/#:~:text=A%202011%20study%20reported%20that,head%20a%20significant%20strengthening%20effect> (accessed 15/05/2020).

The thesis conducts a comparative study of the regulation of sex lubricants for safety in other regions besides the national and international statutes, rules and regulations in chapter 3.²⁵

Most lubricant manufacturers carry out their testing according to the ISO 10993 which is a series of safety biocompatibility standards used by all regulatory bodies to assess the safety of medical devices.²⁶ KEBS being a member of the ISO has adopted this safety standard to regulate sex lubricants used in the Kenyan market.²⁷

The FDA, a federal agency in the USA is mandated to protect public health by among other ways, ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices.²⁸

Since 1976 the FDA classified sex lubricants as either class I or class II medical devices depending on marketing or the claim of the product itself.²⁹ However after 2014, the FDA concluded that sex lubricants are substances that deserve scientific attention owing to a number of issues that arose from the use of some lubricants. One of the key issues behind the regulatory shift was that some sex lubricants with high overall component concentrations (osmolalities) were found to increase the transmission of HIV/STI infections.³⁰

In Europe, sex lubricants are also classified as class IIa medical devices.³¹ This classification is however problematic and is a cause of alarm for many as products classified as medical devices in these jurisdictions are excluded from extensive pre-clinical and clinical testing required to obtain market authorizations for the products.³²

²⁵ Cf Chapter 3 of this LLM Research Project Paper.

²⁶ United Nations Population Fund (2016) “Global Consultation on Personal Lubricants,” at https://cdn.shopify.com/s/files/1/2673/6210/files/Meeting_Report_Global_Consultation_on_Personal_Lubricant_s.pdf (accessed 14/05/2020).

²⁷ International Organization for Standardization (2020) “About Us,” at <https://www.iso.org/about-us.html> (accessed on 21/8/2020).

²⁸ Food and Drug Administration (2018) “What we do” at <https://www.fda.gov/about-fda/what-we-do> (accessed 08/05/2020).

²⁹ Food and Drug Administration (2020) “Product classification” at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NUC> (accessed 14/05/2020).

³⁰ Cf UNFPA (2016) “Global Consultation on Personal Lubricants.”

³¹ UNFPA, *ibid.*

³² Stacey L Wilson, Jamila K Adam and Suresh Babu Naidu Krishna (2017) “Effects of Vaginal Lubricants on *In-Vitro* Progressive Spermatozoa Motility,” 21 *African Journal of Reproductive Health* at 97.

Furthermore, personal lubricant products that claim to moisturize or cleanse have often been considered as cosmetics.³³ In 2003, the FDA reviewed the safety and efficacy of sex lubricants. In the review, they clarified that sex lubricants claiming to decrease pain, enhance sexual pleasure or contain spermicide would be categorized as drugs since they are related to easing discomfort or alleviating a condition which is more or less the mitigation or treatment of disease.³⁴

This categorization was not welcomed by some lubricant manufacturers who argued that the intended use of lubricants is for cosmetic purposes as opposed to treating disease. This opposition stemmed from the fact that having lubricants classified as drugs by the FDA could add a further regulatory burden upon lubricant manufacturers by requiring them to test lubricants for safety.³⁵

From the foregoing, this thesis discusses the regulatory controls that are in place and their limitations if any. It also discusses the disadvantages of having limited or no regulations in Kenya relating to sex lubricants as well as the arising safety concerns of users of these sex lubricants. It makes a comparative analysis with the regulation of sex lubricants in other jurisdictions namely South Africa, Nigeria and from regulatory controls employed by the FDA in the US and the EMA in Europe³⁶ and finally make relevant recommendations for the Kenyan regulatory controls of sex lubricants.

1.2 Statement of the Problem and Issues Arising on Regulating Sex Lubricants for Safety in Kenya

One of the issues arising from this study is that there are limited regulatory controls with regard to sex lubricants in Kenya despite the fact that they are widely used by many sexually active

³³ Cf Geibel (2013) “Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa” *op.cit.*, at 8.

³⁴ FDA (2003) “Over-the-counter drug products; safety and efficacy review,” at <https://www.govinfo.gov/content/pkg/FR-2003-12-31/pdf/03-32102.pdf> (accessed 14/05/2020).

³⁵ Cf. Geibel (2013) “Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa” at 8.

³⁶ Cf Chapter 4 of this LLM Research Project Paper.

individuals and especially postmenopausal women,³⁷ sex workers and men who have sex with men (MSMs).³⁸

Owing to these limited regulatory controls, there is a risk of having sex lubricants in the market that contain harmful ingredients that irritate the body and risk exposing the consumers of these devices to harm. Some studies have shown that some brands of sex lubricants have caused yeast infections in some women while others have made users susceptible to sexually transmitted infections (STIs).³⁹ Other studies have also shown that some lubricants increase the replication of HIV and may cause rectal tissue damage.⁴⁰

Other issues that have arisen include having sex lubricants that are ineffective. In the US, a plaintiff filed a false advertising class action suit against a lubricant manufacturing company that had claimed that its sex lubricants were ineffective and that it did not increase sexual pleasure as it claimed.⁴¹ The plaintiff also claimed that the lubricant in question was not approved by the FDA.

The issue of categorization of lubricants as medical devices by agencies such as the FDA and EMA has also posed challenges. This is due to the fact that some manufactures claim that the purpose of lubricants is not to alter body structure and that the enhancement of sexual pleasure can broadly be interpreted as beautifying.⁴² This is in a bid to avoid stringent regulatory controls arising from categorizing lubricants as medical devices since medical devices are heavily regulated by these agencies.

³⁷ Cf. Obiero, et.al. (2019) “A Comparative Study of Smugel and KY Jelly Vaginal Lubricating Gels,”

³⁸ Cf. Geibel (2013) “Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa,” at 8.

³⁹ Pamina Gorbach, Robert Weiss, Edward Fuchs, Robin Jeffries, Marjan Hezerah, Stephen Brown, et al (2012) “The slippery slope: lubricant use and rectal sexually transmitted infections: a newly identified risk.” *Sexually Transmitted Diseases*
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3244680/#:~:text=Concerns%20about%20the%20effects%20of%20epithelium12%2C%2013%2C14>. (accessed 22/05/2020).

⁴⁰ Population Council (2011) “Population Briefs: Reports on Population Council Research,” at <https://www.popcouncil.org/uploads/pdfs/popbriefs/201108.pdf> (accessed 21/05/2020).

⁴¹ *Tania Warchol (f/k/a Tania Racha) et al. v. Love Honey Inc* Case No. 3:15-cv-00238 [2015]. See also Chapter 4 of this LLM Research Project Paper for a deeper analysis of this case.

⁴² Geibel (2013) “Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa,” *op.cit.*, at 8.

Finally, sex lubricants are commercially categorized differently across countries. Some categorize them as medical devices while others categorize them as cosmetic products. These differences mean that their manufacture, import and export can encounter legal and bureaucratic cross-border delays before reaching users.⁴³

More regulatory controls should therefore be put in place in accordance with the appropriate ISO standards relating to sex lubricants to resolve these issues and to ensure that the safety and sexual and reproductive well-being of users of sex lubricants is protected.

1.3 Research Objectives of the study on Regulating of Sex Lubricants for Safety in Kenya

This thesis seeks to achieve the following general and specific research objectives:

The main research objective of this thesis is to critically analyze the available regulatory controls relating to sex lubricants that ensure their safety.

This thesis seeks to achieve the following three (3) specific objectives.⁴⁴

First, to discuss the national and international legal frameworks and regulations pertaining to sex lubricants in Kenya.

Second, to discuss the limitations arising from the legal frameworks and regulations as well as the safety concerns arising from these limitations in Kenya.

Third, to make recommendations from a comparative study of the US, the EU, South Africa , Nigeria and select international organizations on how to improve the available laws and regulations pertaining to sex lubricants in Kenya.

1.4 Research Questions on Regulating Sex Lubricants for Safety in Kenya

This thesis seeks to answer the following three (3) research questions.⁴⁵

First, what are the national and international legal frameworks and regulations on sex lubricants in Kenya?

⁴³ The New Humanitarian (2013) “Lack of “lube” hurts HIV prevention,” at <https://www.thenewhumanitarian.org/feature/2013/02/21/lack-lube-hurts-hiv-prevention> (accessed 22/05/2020).

⁴⁴ Ben Sihanya (2023) *Sihanya Mentoring Guidelines on LLM Thesis Proposal*, Innovative Lawyering and Sihanya Mentoring, Nairobi & Siaya.

⁴⁵ *Ibid.*

Second, what are the limitations arising from the legal frameworks and regulations? Additionally, what safety concerns arise from these limitations?

Third, what recommendations can be made from the comparative study of the US, the EU, South Africa , Nigeria and select international organizations to improve the available laws and regulations on sex lubricants in Kenya with regard to operationalizing Article 43(1)(a) and Article 46 of the Constitution 2010?

1.5 Hypotheses and Assumptions on Limitations of Regulating Sex Lubricants for Safety in Kenya

This thesis argues that the legal framework and regulations on sex lubricants in Kenya is limited. More regulations should be enacted to ensure that the safety and sexual and reproductive healthcare of users of lubricants are upheld. This thesis proceeds on the following assumptions or hypotheses.

First, adopting a clear legal framework for the regulation of sex lubricants in Kenya is crucial to enhance the protection of sexual and reproductive health rights.

Second, adopting rules and regulations from established international bodies such as the International Organization for Standards (ISO), the Food and Drug Administration (FDA), and the European Medicines Agency (EMA) is key in enhancing the safety of users of sex lubricants in Kenya.

1.6 Review of the Literature, Law, Policy and Content Analysis on Regulating Sex Lubricants for Safety in Kenya

For the purpose of this study, literature means and includes laws, policy guidelines and literature material on the topic.⁴⁶ I discuss, analyze and review some of the literature I have relied on in this study below.

It is important to note that there are hardly any books on the regulation of sex lubricants in Kenya. As a result, this thesis being exploratory will largely rely on medical journal articles on the safety and efficacy of sex lubricants as well as guidelines from ISO, the FDA and the WHO.

⁴⁶ Ben Sihanya (2015) *Ibid*.

Sex lubricants when used come into contact with the mucous membranes of the female and male primary sexual organs.⁴⁷ They are then absorbed in the body and can enter the bloodstream. As a result, these products should be comprehensively regulated to ensure that consumers of these devices access quality, safe and efficient products for their sexual and reproductive well-being.

Numerous studies have reported that the regulatory environment of sex lubricants is varied from state to state and as a result, there is a dearth of documentation of the human safety of sex lubricants.⁴⁸ This is particularly apparent in developing countries which lack the capacity to monitor and review the safety of pharmaceutical products thus often relying in guidance from stringent regulatory bodies such as the FDA and the EMA.⁴⁹ Kenya falls into this category with regard to the regulation of sex lubricants.

Sex lubricants are generally classified either as medical devices or as cosmetics depending on the marketing or claim of sex lubricants. In the US and Europe, lubricants are classified as class II or class IIa medical devices respectively.⁵⁰ As such they undergo rigorous testing before being introduced to the market. In the US, manufacturers of these devices must submit 510(k) clearance to the FDA, demonstrate safety and effectiveness and show that they are reasonably equivalent to a legally marketed device.⁵¹ However the testing conducted on these devices isn't as extensive as testing conducted on drug products.⁵²

Those lubricants that claim to be used as cosmetics are generally classified as such. This is the case in Canada where manufacturers must complete a Cosmetic Notification Form and provide

⁴⁷ Bart Desmedt (2019) "Consumer protection provided by the European medical device and cosmetic legislation for condoms and lubricants" *Regulatory Toxicology and Pharmacology Journal* 106-112.

⁴⁸ Scott Geibel (2013) "Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa," *Journal of the International AIDS Society* 2-3 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3708353/#:~:text=A%202011%20study%20reported%20that,head%20a%20significant%20strengthening%20effect> (accessed 15/05/2020).

⁴⁹ Geibel (2013) *ibid.*

⁵⁰ Cassandra Laurie and Eduardo Franco (2020) "The Potential Harms of Personal Lubricants" *Brazilian Journal of Sexually Transmitted Diseases* 1-4 at <https://www.bjstd.org/revista/article/view/1270/1318> (accessed 26/11/2023).

⁵¹ Laurie and Franco (2020), *ibid.*

⁵² Nicole Weendee (2014) "A question for women's health: Chemicals in feminine hygiene products and personal lubricants" *Environmental Health Perspectives* A70-A75 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948026/> (accessed 26/09/2020).

details on ingredients used in the manufacture of the lubricants.⁵³ Regulation of cosmetics is less stringent as compared to the regulation of drugs or medical devices.

Much study has been done on the efficacy and safety of sex lubricants. The efficacy and safety of these products is mainly tested in two (2) ways. One, by exclusively conducting laboratory tests on the lubricants⁵⁴ or by relying on the use of these devices in study populations and conducting clinical tests on them thereafter.⁵⁵

Studies have revealed that some lubricants contain ingredients that may tamper with the vaginal environment when used by women during sex. Dezzutti explains in her article that some lubricants are hyperosmolar (their component concentration (osmolality) are higher than the body's cells) meaning that they tend to pull water out of the vaginal epithelium causing the cells to shrink and shrivel.⁵⁶ She states that these changes to the vaginal environment can lead to toxic effects and eventually transmission of sexually transmitted infections such as HIV.⁵⁷

The World Health Organization (WHO) in its advisory note indicated that personal lubricants are generally regarded as low-risk products and as a result are subjected to limited regulatory controls.⁵⁸ It stated that due to its classification by the FDA and EMA as a medical device, safety testing is often restricted to vaginal and penile sensitization studies in the rabbit. Moreover, the WHO indicated a number of potential safety issues emanating from the studies, key among them being vaginal and epithelial damage.⁵⁹ This means that the inner lining of the vagina might be damaged if low quality sex lubricants are used in the vaginal area.

⁵³ Cf Laurie and Franco (2020) "The Potential Harms of Personal Lubricants".

⁵⁴ See Ellen Wilkinson, Melissa Herbst-Kralovetz et.al (2019) "Personal and Clinical Vaginal Lubricants: Impact on Local Vaginal Microenvironment and Implications for Epithelial Cell Host Response and Barrier Function" 220 *The Journal of Infectious Diseases* 2009-2018 at <https://academic.oup.com/jid/article/220/12/2009/5563809> (accessed 12/07/2023).

⁵⁵ Santiago Palacios, Sarah Hood, Temitayo Abakah-Phillips et.al. (2023) "A Randomized Trial on the Effectiveness and Safety of 5 Water-based Personal Lubricants" 20 *The Journal of Sexual Medicine* 498-506 at <https://academic.oup.com/jsm/article/20/4/498/7035572?login=false> (accessed 12/07/2023).

⁵⁶ Charlene Dezzutti, Elizabeth Brown, Bernard Moncla (2012) "Is wetter better? An evaluation of over-the-counter personal lubricants for safety and anti-HIV-1 activity," at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0048328> (accessed 28/09/2020).

⁵⁷ Dezzutti, Brown and Moncla (2012) *ibid*.

⁶² Lauren K Wolf (2012) "Studies raise questions about safety of personal products," at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html> accessed (18/05/2020).

⁶² Lauren K Wolf (2012) "Studies raise questions about safety of personal products," at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html> accessed (18/05/2020).

A technical review was then conducted at the United Nations Population Fund (UNFPA) Global Consultation on Lubricants in 2016. The review indicated that the uses of sex lubricants are varied. They include the improvement of lubrication and enhancement of sexual pleasure during vaginal or rectal intercourse, the reduction of pain and the risk of vaginal or rectal tearing, and the amelioration of vaginal dryness.⁶⁰

However, the review also indicated that studies in recent years have shown that some lubricants have caused irritation and epithelial damage to the rectal or vaginal lining increasing the susceptibility of its users to transmitting HIV and other Sexually Transmitted Infections (STIs).⁶¹

Lauren Wolf in her article also raises these concerns and further indicates that the same lubricants shown to transmit HIV and STIs are ironically the very same ones that are being eyed as aids that could protect people from HIV.⁶²

Various other safety concerns arise from the use of sex lubricants as published in a number of studies. Some areas of concern include the pH, the classification and even the types of sex lubricants available in the market.⁶³

A comparative analysis of the safety and efficacy of sex lubricants in other African countries indicated alarming results. For example, in South Africa the use of lubricants by heterosexual individuals and MSM during sex is neither widespread nor common.⁶⁴ This is because of a myriad of reasons such as pricing of these devices⁶⁵ and even ignorance of the availability of these devices.⁶⁶ In one paper, it was noted that in the rare instance that lubricants were used

⁶² Lauren K Wolf (2012) “Studies raise questions about safety of personal products,” at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html> accessed (18/05/2020).

⁶² Lauren K Wolf (2012) “Studies raise questions about safety of personal products,” at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html> accessed (18/05/2020).

⁶² Lauren K Wolf (2012) “Studies raise questions about safety of personal products,” at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html> accessed (18/05/2020).

⁶³ Cf Chapter 3 of this Research Project Paper.

⁶⁴ Mathew Lee, Theo Sandfort et.al. (2017) “Breakage is the norm: use of condoms and lubrication in anal sex among Black South African men who have sex with men” 19 *Culture, Health & Sexuality* 501-514 at <https://www.tandfonline.com/doi/epdf/10.1080/13691058.2016.1239134?needAccess=true&role=button> (accessed 07/08/2023).

⁶⁵ Kabelo Maleke, Nosipho Makhakhe et.al. (2017) “HIV risk and prevention among Men who have Sex with Men in rural South Africa” *African Journal of AIDS Research* 31-38 at <https://doi.org/10.2989/16085906.2017.1292925> (accessed 10/08/2023).

⁶⁶ *Ibid.*

during sexual intercourse, non-commercial lubricants (such as body lotions, food items such as yoghurt and chocolate spread)⁶⁷ most of which are neither condom compatible nor intended for internal use would be used.⁶⁸

This was more or less the finding in studies conducted in Nigeria on the safety and efficacy of sex lubricants. In one of the studies conducted in Lagos, it was noted that the use of lubricants by MSM is quite low despite the fact that 62.9% of the study participants reported access to both condoms and lubricants.⁶⁹ Some of those that did use lubricants during sex were reported to have used non water-based lubricants with petroleum jelly being the most common alternative lubricant.⁷⁰

Nationally, the policy guidelines and reports governing sex lubricants hardly mention the safety concerns arising from the use of such devices. Much focus is placed on the availability of sex lubricants to the public and particularly to men who have sex with men (MSMs).

The Kenya National Commission on Human Rights (KNCHR) conducted a public inquiry into the violation of sexual and reproductive health rights in Kenya. In its report, it indicated that users of sex lubricants specifically MSMs have limited access to Sexual and Reproductive Health (SRH) services due to their high cost.⁷¹ This inhibition leaves many people to resort to other products such as petroleum products, baby oils and lotions for lubrication.⁷²

As detailed above, most studies conducted are on the safety and efficacy of sex lubricants rather than on the regulatory controls employed in regulating these devices. There is a need to develop more robust regulatory controls on sex lubricants and conduct studies on the same particularly in developing countries.

⁶⁷ *Ibid*

⁶⁸ Cf Lee, Sandfort et.al. (2017) “Breakage is the norm: use of condoms and lubrication in anal sex among Black South African men who have sex with men.”

⁶⁹ Trevor Crowell, Stephan Baral et.al. (2019) “Time to Change the Paradigm: Limited Condom and Lubricant Use among Nigerian Men who have Sex with Men and Transgender Women despite Availability and Counseling” at *Annals of Epidemiology* 11-19 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6732794/> (accessed 30/08/2023).

⁷⁰ *Ibid*.

⁷³ Article 43 (1) (a) of the Constitution, 2010. Article 46 also guarantees consumer rights of users of sex lubricants in Kenya.

⁷³ Article 43 (1) (a) of the Constitution, 2010. Article 46 also guarantees consumer rights of users of sex lubricants in Kenya.

1.7 Justification, Significance and Limitations on the study of Regulating Sex Lubricants for Safety in Kenya

Sex lubricants are medical devices that are an integral part in the sexual and reproductive healthcare of individuals. As has been discussed earlier, sexual and reproductive health care has been regarded as a human right in the Constitution of Kenya, 2010⁷³, in relevant statutes and policies as well as in various international and regional instruments to which Kenya is party.

A reading of the laws and regulations governing sex lubricants in Kenya reveals that there are gaps in relation to their regulation for safety. Statutes such as the Standards Act, the Health Act, the Consumer Protection Act and the Reproductive Health Bill provide for the regulation of goods for safety including medical devices. However, they do not expressly list sex lubricants as one of the goods that are to be regulated for safety.

National reproductive health policies⁷⁴, strategies⁷⁵ and reports⁷⁶ place an obligation on the state to protect, respect and fulfill the sexual and reproductive health rights of Kenyans. They barely have clauses that provide for the regulation of sex lubricants for safety. The Kenya National Commission on Human Rights report however recognizes that the cost of sex lubricants and other commodities such as condoms are one of the barriers that sexual minorities face in accessing Sexual Reproductive Health (SRH) services.⁷⁷

Therefore the literature, law and policy on sex lubricants have gaps in relation to regulating sex lubricants for safety. This thesis therefore seeks to analyse the national and international legal framework and regulations governing sex lubricants for safety. It also seeks to identify the safety challenges arising from the regulatory gaps in regulating sex lubricants. The thesis therefore encourages Parliament to enact legislation that will specifically regulate sex lubricants in Kenya for safety.

⁷³ Article 43 (1) (a) of the Constitution, 2010. Article 46 also guarantees consumer rights of users of sex lubricants in Kenya.

⁷⁴ Cf. National Reproductive Health Policy 2007.

⁷⁵ Cf. National Reproductive Health Strategy 2014-2018.

⁷⁶ Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

⁷⁷ *Ibid.*

1.8 The Theoretical Framework of the study on Regulating Sex Lubricants for safety in Kenya

This thesis draws from concepts and theories that form the basis of the study. I shall delve into theories of regulation while focusing specifically on the regulation of sex lubricants.

1.8.1 Theorizing Regulation of Sex Lubricants for Safety in Kenya

Economic regulation affects the economy at a macro-level as they have the potential of altering the economic structure.⁷⁸ At a micro-level, economic agents are likely to experience welfare gains or losses emanating from policy regulations which ultimately results in improvement or reduction of individual welfare.⁷⁹

The regulatory framework that is used in a society also affects the competition in the provision of goods and services within a sector. It is therefore important to theorize the regulation of sex lubricants for safety in Kenya to understand how the products will be affected by regulation.

There are two broad theories governing economic theories of regulation. These are namely the public interest theory of regulation, and the private interest theory of regulation.⁸⁰

According to the public interest theory of regulation, legislators and all those responsible for coming up with and implementing regulations should have a collective desire to promote the general welfare of the community when legislating.⁸¹ This theory argues that the welfare of the community is greater than and prevails over the welfare of regulated stakeholders in a society.

Government regulation is therefore an instrument for overcoming the disadvantages of imperfect competition, unbalanced market operation, missing markets and undesirable market results in public interest theories of regulation.⁸² In the case of sex lubricants, government regulation would ensure that sex lubricants are readily available in the market for the use, benefit, health and safety of the general populace.

⁷⁸ Institute of Economic Affairs (2020) *Regulation and Competition* at <https://www.ieakenya.or.ke/focus-areas/economic-regulation-policy> (accessed 23/09/2020).

⁷⁹ *Ibid.*

⁸⁰ Bronwen Morgan and Karen Yeung (2003) *An Introduction to Law and Regulation: Text and Materials*, Cambridge University Press at 8.

⁸¹ Morgan and Yeung, *ibid.*

⁸² Johan den Hertog (2000) "General Theories of Regulation," in Boudewijn Bouckaert and Gerrit De Geest (eds) *Encyclopedia of Law and Economic, Vol III: The Regulation of Contracts*.

Private interest theories of regulation on the other hand recognize that regulation is beneficial to particular groups of the society as opposed to the general community. This theory contends that specific groups of society use political and law-making process to secure regulatory benefits for themselves.⁸³ Therefore in the case of sex lubricants, manufacturers of these medical devices are set to profit considerably from the manufacturing of the devices. They therefore favour regulation that maximizes profit.

1.9 Research Methodology: Design, Methods and Techniques on the Regulation of Sex Lubricants for Safety in Kenya

This thesis studies the regulation of sex lubricants for safety in Kenya. The main areas of research include literature by scholars, the law and policy guidelines. This shall therefore involve gathering and analyzing information already published in print media and the internet. These resources are found in libraries, newspaper articles and other online sources.

The thesis also conducts a comparative analysis of the regulation of sex lubricants in other jurisdictions namely, South Africa and Nigeria and in regulatory agencies such as the FDA, the EMA and the ISO as reported in journal articles and the respective regulatory agencies websites and reports.

1.10 Originality, Contribution and Scope of the Study on the Regulation of Sex Lubricants in Kenya

This thesis is largely exploratory as there has been little literature on the subject. As such it is original and propounds suggestions for further research.

It seeks to contribute to the development of further interventions relating to the regulation of sex lubricants for safety in Kenya by highlighting the available frameworks that are already in place and their limitations. Through a comparative analysis with regulations from other jurisdictions as well as from organizations such as the WHO and the ISO, this thesis seeks to make recommendations on how the relevant agencies can improve the regulatory framework for sex lubricants in Kenya.

⁸³ Morgan and Yeung, (2003) *An Introduction to Law and Regulation: Text and Materials op.cit.*, at 10.

As has been previously discussed, there are limited regulatory controls governing sex lubricants in Kenya. As such, this thesis proposes that a national framework on the regulation of sex lubricants should specifically be put in place to safeguard the sexual and reproductive health of users of these devices.

The study will therefore scrutinize our laws as well as those from other jurisdictions such as the US and the EU, South Africa , Nigeria and those of organizations such as the WHO and ISO.

1.11 Challenges of the Study and Prospects on Regulating Sex Lubricants for Safety in Kenya

There are at least two (2) challenges I expect to face in the conduct of this study:

First, as has been alluded to earlier, this thesis is largely exploratory in nature. As a result, it has been a challenge finding reference material especially from African literature on the regulation of sex lubricants for safety specifically in Kenya.

Second, the relevant legal instruments on sex lubricants such as the Health Act, the proposed Reproductive Healthcare Bill and the various reproductive health policies previously discussed do not define what these devices are much less their regulation. This situation therefore requires seeking guidance from other jurisdictions and international organizations such as the WHO in order to better regulate these devices for safety in Kenya.

1.12 Chapter Outline on Regulating Sex Lubricants for Safety in Kenya

This thesis is divided into the following five chapters as indicated below.

Chapter 1: Introduction on the study on the Regulation of Sex Lubricants in Kenya

This chapter addresses the research methodology on the study on regulation of sex lubricants in Kenya. The chapter conceptualizes and problematizes the issue, identifies the research objectives, research questions and research hypothesis. It will also address the literature review on the area as well as the conceptual and theoretical framework on the regulation of sex lubricants for safety in Kenya.

Chapter 2: The National and International Framework of and Limitations of the Regulation of Sex Lubricants in Kenya

This chapter will discuss the regulation of sex lubricants nationally and in other jurisdictions and their limitations. It will address the first objective as well as the first research question of this thesis.

Chapter 3: The Safety Concerns arising from the Regulation of Sex Lubricants in Kenya

This chapter will discuss the safety concerns that arise when sex lubricants are not properly regulated. It will briefly discuss a class action suit⁸⁴ lodged in the US over ineffectiveness of a sex lubricant.

Chapter 4: Comparative Study on the Regulation of Sex Lubricants in the USA and United Kingdom

This chapter addresses the third research objective by making a comparative analysis of the varied regulations of sex lubricants in the US, the EU, South Africa and Nigeria. It will then identify lessons that Kenya can learn on the regulation of these devices.

Chapter 5: Summary of Findings, Conclusions and Recommendations on the Regulation of Sex Lubricants in Kenya

This chapter gives a summary of the study. It shall discuss the findings of the study and the recommendations to the regulation of sex lubricants in Kenya.

⁸⁴ *Tania Warchol (f/k/a Tania Racha) et al. v. Love Honey Inc* Case No. 3:15-cv-00238 [2015].

CHAPTER 2
THE LEGAL FRAMEWORK OF REGULATING SEX LUBRICANTS
FOR SAFETY IN KENYA

2.1 Introduction on the Legal Framework of Regulating Sex Lubricants for Safety in Kenya

The overarching research question and argument of this chapter is that there are limited national and international frameworks on the regulation of sex lubricants.⁸⁵

This Chapter 2 addresses the first research objective which is to critically analyze the current national and international legal frameworks and regulations pertaining to sex lubricants.

This Chapter seeks to answer the second research question which is what is the current national and international legal frameworks and regulations on sex lubricants in Kenya?

In this Chapter I discuss the legal framework of regulation of sex lubricants in Kenya as well as the regional and international framework. From this discussion, we will be able to appreciate the necessary regulations that Kenya can adopt in order to ensure that users of lubricants access lubricants that are safe to use and are of good quality.

2.2 Constitutional Provisions on the Regulation of Sex Lubricants in Kenya

Sexual and reproductive healthcare is defined as a state of complete physical, mental and social well-being in relation to all aspects of sexuality and reproduction, not merely the absence of disease, dysfunction or infirmity.⁸⁶ Further, the WHO expands this working definition and states that sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence.⁸⁷

Sex lubricants are integral in the sexual and reproductive healthcare of individuals as they are directly used in the genitalia of its users. As such, any anomaly in their formulation may

⁸⁵ Ben Sihanya, (2023) *Sihanya Mentoring Guidelines on LLM Thesis Proposal*, Innovative Lawyering and Sihanya Mentoring, Nairobi & Siaya.

⁸⁶ United Nations Population Fund (2022) “Sexual and Reproductive Health,” at <https://www.unfpa.org/sexual-reproductive-health#readmore-expand> (accessed 20/7/2022).

⁸⁷ World Health Organization (2022) “Sexual and Reproductive Health and Research (SRH)” at <https://www.who.int/teams/sexual-and-reproductive-health-and-research/key-areas-of-work/sexual-health/defining-sexual-health> (accessed 20/7/2022).

adversely affect the health of its users. For example, the United Nations Population Fund (UNFPA) in its report⁸⁸ found that some sex lubricants with high overall component concentrations (osmolalities) were found to increase the transmission of HIV/STI infections.⁸⁹ It is therefore prudent that Governments ensure that sex lubricants in their market are of good quality and are safe to use.

Sexual and reproductive healthcare in Kenya is a social right that has been enshrined in article 43 of the Constitution, 2010. It provides that every person has the right to the highest attainable standard of health including the right to health care services and including reproductive health care.⁹⁰ This right is an inclusive right that extends to and encompasses a wide range of factors that can help those to whom the right accrues to live a healthy life.⁹¹

Consumers of sex lubricants are further protected under Article 46 of the Constitution which enshrines consumer protection rights.⁹² These rights encompass the right to goods that are of reasonable quality, to information necessary for them to gain full benefit from the goods and the right to compensation for injury resulting from the defects of the goods. This article is further solidified by the Consumer Protection Act, 2012⁹³ which this thesis delves more into in section 2.3.

The right to information to consumers necessary for them to gain full benefit from goods is further entrenched in article 35 of the Constitution. It provides that every citizen has the right of access to information held by the State and information held by another person and required for the exercise or protection of any right or fundamental freedom. The Access to Information Act, 2016⁹⁴ gives effect to this provision of the Constitution and is discussed in detail in section 2.3 of this thesis.

⁸⁸ United Nations Population Fund (2022) “Safe Lubricants for All - Procurement Specifications for Lubricants Used with Male and Female Condoms (Technical Brief)” at <https://www.unfpa.org/publications/safe-lubricants-all-procurement-specifications-lubricants-used-male-and-female-condoms> (accessed 12/07/2023).

⁸⁹ United Nations Population Fund (2016) “Global Consultation on Personal Lubricants,” at https://cdn.shopify.com/s/files/1/2673/6210/files/Meeting_Report_Global_Consultation_on_Personal_Lubricant_s.pdf (accessed 18/08/2020).

⁹⁰ Constitution of Kenya 2010, article 43(1)(a).

⁹¹ Center for Reproductive Rights (2021) *Access to SRHR Information by Women and Girls in Kenya: Assessment of Nairobi, Bungoma, Homabay, Kericho, and Kilifi Counties*, Nairobi.

⁹² Constitution of Kenya 2010, Article 46 (1)(a-d).

⁹³ Consumer Protection Act, 2012.

⁹⁴ Access to Information Act, 2016.

The National and County Governments through the Ministry of Health and the various County Departments of Health respectively are mandated by the Constitution to conduct their mutual relations on the basis of consultation and cooperation⁹⁵. These mandates are further clarified in the 4th Schedule of the Constitution that elaborates the functions of the two levels of Government with regard to healthcare.

The National Government has the mandate to oversee consumer protection, including standards for social security and professional pension plans, national referral health facilities and to formulate health policies. Some of the health policies formulated by the National Government are discussed in section 2.3 of this thesis.

As health care is devolved,⁹⁶ County Governments have the mandate to oversee county health services which include county health facilities and pharmacies, ambulance services, promotion of primary health care, licensing and control of undertakings that sell food to the public, veterinary services (excluding regulation of the profession), cemeteries, funeral parlours and crematoria; and refuse removal, refuse dumps and solid waste disposal.

From the foregoing, it is evident that the National Government is primarily responsible for the enhancement and promotion of sexual and reproductive health rights in Kenya.

Finally, the Constitution at article 2(5) allows general rules of international law to form part of the laws of Kenya. Article 2(6) also allows any treaty or convention ratified by Kenya to form part of the laws of Kenya. Some of those general rules and treaties relating to reproductive healthcare that are part of Kenyan law are discussed in section 2.5 of this thesis.

2.3 Statutory Provisions and Policies on the Regulation of Sex Lubricants in Kenya

There are a number of statutes that provide general protection to persons with regard to sexual and reproductive healthcare. Through the discussion in this section, it will be evident that there lacks specific statutes that provide for reproductive rights of Kenyans and in particular, the regulation of devices such as sex lubricants.

⁹⁵ Constitution of Kenya 2010, article 6(2).

⁹⁶ The Council of Governors (2022) “Health is devolved, allow counties the mandate to implement the policies and legislation) at <https://cog.go.ke/component/k2/item/241-health-is-devolved-allow-counties-the-mandate-to-implement-the-policies-and-legislations> (accessed 22/02/2022).

The Health Act, 2017 was enacted to establish a unified health system, to co-ordinate the relationship between the National and County Government health systems⁹⁷, to provide for regulation of healthcare service and its service providers, health products and health technologies. One of the objectives of the Act is to protect, promote, respect and fulfill the health rights of all persons in Kenya including their reproductive health.⁹⁸ As such, the Act recognizes that reproductive health care is a right. The right extends to men and women of reproductive age and it gives these groups of people the right to have access to reproductive health services.⁹⁹ The Act only mentions family planning services directly. However it is silent on other reproductive health services such as lubricants, pre-natal care, prevention of abortion, abortion after-care among others.

The Act gives effect to the 4th Schedule of the Constitution by further elaborating on the duties of the National and County Government with regard to healthcare.¹⁰⁰ As previously mentioned, the National Government has the primary mandate of promoting sexual and reproductive health rights as its functions is among others to develop health policies, laws and administrative procedures and programmes in consultation with county governments, health sector stakeholders and the public for the progressive realization of the highest attainable standards of health including reproductive health care and the right to emergency treatment.¹⁰¹

The role of County Governments on the other hand, is to ensure that there is health service delivery including reproductive health services. It has been suggested that this can be achieved in four (4) ways namely, availing a network of healthcare facilities. Second, ensuring that the facilities are functional with competent and motivated staff. Third, ensuring that there is a supply of essential medicines and fourth, ensuring that funds meant for the operation and maintenance of health facilities must reach the facilities on time.¹⁰²

A report by the UNFPA indicates that there has been progress in the delivery of reproductive health services in Kenya particularly with the introduction of the Universal Health Coverage

⁹⁷ Cf. Constitution of Kenya, 2010. See also the Health Act, 2017.

⁹⁸ Health Act 2017, s 3(b).

⁹⁹ *Ibid* at s 6(1)(a).

¹⁰⁰ Cf. Constitution of Kenya, 2010 at 8.

¹⁰¹ Health Act 2017, s 15 (1)(a).

¹⁰² Caroline Mwangi (2013) *Accessibility to the Kenyan health care system Barriers to accessing proper health care* PhD Thesis, Arcada University.

(UHC) by the Government of Kenya in four pilot counties namely Nyeri, Kisumu, Isiolo and Machakos in 2018.¹⁰³

UHC is yet to be fully implemented in all the 47 counties and is currently facing a number of teething problems¹⁰⁴ but once fully implemented it is seen as providing a unique opportunity for the progressive realization of universal access to SRHR and the realization of the right to the highest attainable standard of health for Kenya.¹⁰⁵

Furthermore, Part VII of the Act covers the regulation of health products and health technologies. It states that there shall be established a single regulatory body mandated to regulate health products and health technologies whose functions are among others to regulate these health products and health technologies.¹⁰⁶ The term health products has however not been defined in the Act. The Pharmacy and Poisons Act, Chapter 244¹⁰⁷ is the only statute that defines what health products are. This thesis uses this definition as guidance to the study.

Section 2 of the Pharmacy and Poisons Act interprets health products to include human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products.

This definition broadens the scope of the term health products and does not specifically define it. It has been argued that health products could be outputs that are not directly used to treat or are not necessarily therapeutic and could be nutritional.¹⁰⁸

As previously discussed in Chapter 1 of this thesis, this study adopts the FDA's classification of sex lubricants as medical devices¹⁰⁹. The Pharmacy and Poisons Act defines a medical

¹⁰³ United Nations Population Fund (2022) "Integrating sexual and reproductive health services within Universal Health Coverage: Lessons from Kenya," at <https://kenya.unfpa.org/en/news/integrating-sexual-and-reproductive-health-services-within-universal-health-coverage-lessons> (accessed 27/11/2023).

¹⁰⁴ Lisa Owino, Annetter Wangong'u et.al. (2020) "The missing link in Kenya's universal health coverage experiment: a preventive and promotive approach to SRHR," *Sexual Reproductive Health Matters* at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7887766/> (accessed 28/11/2023).

¹⁰⁵ *Ibid.*

¹⁰⁶ Health Act 2017, s 62.

¹⁰⁷ Pharmacy and Poisons Act, Chapter 244 the Laws of Kenya.

¹⁰⁸ Maurice Oduor (2017) "A critical overview of the Health Act, 2017," at <https://dx.doi.org/10.2139/ssrn.3126423> (accessed on 21/8/2020).

¹⁰⁹ Cf Chapter 1 of this LLM Research Project Paper.

device¹¹⁰ in section 2 as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article-

- a) intended by the manufacturer to be used, alone or in combination, for humans or animals for—
 - i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 - iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
 - iv. supporting or sustaining life;
 - v. control of conception;
 - vi. disinfection of medical devices; or
 - vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
- b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

This thesis adopts the above definition and defines a sex lubricant as a device that is intended by the manufacturer to be used alone or in combination for humans for support of a physiological process, the process being sex.

This thesis therefore argues that the term health products includes sex lubricants as they are generally regarded as medical devices. This thesis further argues that the regulatory body mentioned in the Health Act and relevant guidelines¹¹¹ should also regulate sex lubricants.

The Health Act is a commendable piece of legislation but it has some gaps, specifically in areas pertaining to sexual and reproductive health. To resolve this issue, the Kenyan Senate proposed

¹¹⁰ Pharmacy and Poisons Act, Cap 244 Laws of Kenya.

¹¹¹ Ministry of Health (2020) *Guidelines on Management of Health Products and Technologies in Kenya* at http://guidelines.health.go.ke:8000/media/Guidelines_on_Management_of_Health_Products_and_Technologies_in_Kenya_-_October_2020.pdf (accessed 01/11/2020).

a Reproductive Healthcare Bill, 2019.¹¹² The Bill in its preamble states that it seeks to provide for the right to reproductive health care, to set the standards of reproductive health and to provide for the right to make decisions regarding reproductive health.

Similar to the Constitution and the Health Act, the Bill provides a framework for the protection and advancement of reproductive health rights for every person.¹¹³ It further provides a legal framework for various areas in the reproductive health of individuals such as abortion, maternal healthcare, assisted reproduction among others. However, similar to the Health Act, it is silent on the issue of personal lubricants or any other related medical devices.

The Bill has faced a number challenges which explain why it is yet to be enacted into law. The Ministry of Health termed it as being “fundamentally defective and vague on the emotive technical issues of sexual and reproductive healthcare rights (SRHR)” and called for its withdrawal.¹¹⁴ Suffice to say, the Bill has not been terminated.

There is a proposed Kenya Food and Drugs Authority Bill which sought to establish the Kenya Food and Drugs Authority. If enacted, the Bill would mandate the Authority to provide the regulation and management of drugs, medical devices and other health technologies.¹¹⁵ The Bill defines health products and technologies to include among other therapeutic cosmetics, medical devices including radiation-emitting devices.¹¹⁶ It can therefore be argued that sex lubricants are included in this definition as they are regarded as medical devices.¹¹⁷

The Bill is therefore the only piece of legislation that expressly mentions the regulation of medical devices. However, the Bill has faced some challenges with some stakeholders

¹¹² Henry Makori (2020) Explainer: Reproductive Healthcare Bill, 2019 *The Star*, 21st September, 2020 at <https://www.the-star.co.ke/opinion/2020-09-21-explainer-reproductive-healthcare-bill-2019/> (accessed on 19/7/2022).

¹¹³ Reproductive Healthcare Bill 2019, s 3(a).

¹¹⁴ Edwin Mutai (2020) Health Ministry wants abortion bill withdrawn for more talks *Business Daily*, 11th August, 2020 at <https://www.businessdailyafrica.com/bd/economy/health-ministry-wants-abortion-bill-withdrawn-for-more-talks-2298308> (accessed on 19/7/2022).

¹¹⁵ Kenya Food and Drugs Authority Bill, 2019.

¹¹⁶ *Ibid* at s2.

¹¹⁷ Cf Chapter 1 of this thesis.

maintaining that legislation and regulations on the administration of food and drugs should be separated into two different acts.¹¹⁸

Another statute that is crucial in the regulation of sex lubricants is the Consumer Protection Act, 2012.¹¹⁹ Section 2 of the Act defines a consumer as a person to whom particular goods or services are marketed in the ordinary course of the supplier's business. Therefore buyers and users of sex lubricants can be considered as consumers as per the definition in the Act. They therefore derive consumer rights as enumerated by the Constitution¹²⁰ and the Act.¹²¹

The Act further provides for additional consumer rights. These include the right to commence legal action on behalf of a class of persons in relation to any contract for the supply of goods or services to the consumer, the right to goods that are of reasonable merchantable quality and the right to complain with regard to quality, among others.¹²² This Act ensures that users of sex lubricants can seek relief from the courts if the lubricants are of an undesirable quality. The Standards Act, Cap 496 is an Act of Parliament that seeks to promote the standardisation of the specification of commodities and to provide for the standardisation of commodities and codes of practice. The Act established the Kenya Bureau of Standards (KEBS) which is an institution that this chapter will delve into detail in the next section 2.4.

This Act is important as it establishes the standards on goods ensuring that consumers access goods that are of reasonable quality under the Consumer Protection Act, 2012 as well as ensuring that consumers access goods that are safe and reliable. The Act was enacted in 1973 and might be outdated in some areas. For example, the Act is not aligned with the contemporary world as it lacks the definition of emerging terminologies and new aspects of market surveillance.¹²³ Further, the penalties in the Act are not in tandem with the offences owing to the increase in the value of the shilling since 1973. As a result, KEBS is reviewing the Act and

¹¹⁸ Bernardine Mutanu (2020) Food and drug agency will put lives at risk, say experts *Daily Nation*, 17th March, 2020 at <https://www.nation.co.ke/health/Food-and-drug-agency-puts-lives-at-risk--Players/3476990-5494506-oc988vv/index.html> (accessed 21/08/2020).

¹¹⁹ Consumer Protection Act, 2012.

¹²⁰ Cf. Constitution of Kenya, 2010 at 4.

¹²¹ Cf. Consumer Protection Act, 2012 at 21.

¹²² *Ibid*, part II.

¹²³ Joseph Muchiri (2019) Reviewed Standards Act to improve goods and services for Kenyans *The Standard*, 18th April, 2019 at <https://www.standardmedia.co.ke/business/article/2001321563/reviewed-standards-act-to-improve-goods-and-services-for-kenyans#> (accessed on 21/8/2020).

is in the process of developing a National Quality Policy that will be tasked with enhancing standardization.¹²⁴

The Standards Bill, 2019 further ensures that proper standards are met with regard to the quality of sex lubricants. The Bill lays out the importance of having standards in clause 14 to include among others: safeguarding health and ensuring safety of human beings, ensuring fitness for purpose of products and services, product protection and prevention of deceptive practices. The Bill also seeks to establish a standards tribunal which shall have the jurisdiction to among other things, hear and determine complaints arising out of any breach of the quality of goods. The tribunal will therefore offer a reprieve for users of sex lubricants in case of any harm they occasion as a result of using the devices.

The Access to Information Act, 2016 is yet another piece of legislation that is crucial in ensuring that users of sex lubricants have access to information on their sexual and reproductive health rights. This is important as it enables consumers of sex lubricants to purchase these products armed with information about their quality, use, and components used in the manufacturing of these products.

The Act has the objective to provide a framework for both public and private entities to proactively disclose information that they hold.¹²⁵ This thesis argues that this provision extends to manufacturers of sex lubricants.

Finally, there are a number of policies that generally recognize the reproductive health rights of people in Kenya. These include the Implementation Guidelines for the Kenya Quality Model for Health 2011,¹²⁶ the Kenya Health Sector Strategic and Investment Plan, July 2013 - June 2017,¹²⁷ the National Reproductive Health Strategy 2009-2015,¹²⁸ the National Reproductive

¹²⁴ *Ibid.*

¹²⁵ Access to Information Act 2016, s3(b).

¹²⁶ Ministry of Medical Services and Ministry of Public Health and Sanitation (2011) *Implementation Guidelines for the Kenya Quality Model for Health 2011*, Nairobi.

¹²⁷ Ministry of Health (2014) *Kenya Health Sector Strategic and Investment Plan, July 2013 - June 2017*, Nairobi.

¹²⁸ Ministry of Medical Services and Ministry of Public Health and Sanitation (2009) *National Reproductive Health Strategy 2009-2015*, Nairobi.

Health Policy 2007,¹²⁹ the National Reproductive Health Policy, 2022-2032¹³⁰ and the National Reproductive Health Strategy, 2014-2018.¹³¹ They all place an obligation on the state to protect, respect and fulfill the sexual and reproductive health rights of Kenyans.¹³²

The Pharmacy and Poisons Board published its guidelines on the registration of medical devices in January 2022.¹³³ The guidelines indicate that medical devices are categorized in four (4) classes namely, Class A, B, C and D based on the risk in relation to their intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.¹³⁴

However, just like the various statutes discussed above, these policies barely provide for the regulation of sex lubricants. Mention of sex lubricants is only found in the Kenya National Commission on Human Rights Report of 2012.¹³⁵ The report recognizes that one of the barriers sexual minorities face in accessing Sexual Reproductive Health (SRH) services is the cost of commodities such as condoms, lubricants or screening and treatment for STIs. Other than that, the regulation of sex lubricants is not mentioned.

From the discussion, it is evident that the statutes that are in place do not specifically address the issue of regulation of sex lubricants in Kenya. There is need to enact a specific law that will tackle this issue to ensure the safety of users of sex lubricants in Kenya is guaranteed.

The next section 2.4 tackles the institutional framework on the regulation of sex lubricants in Kenya.

¹²⁹ National Reproductive Health Policy of 2007, 9 at <http://csakenya.org/wp-content/uploads/2016/10/National-Reproductive-Health-Policy-booklet-2007.pdf> (accessed 13/08/2020).

¹³⁰ Ministry of Health (2022) *The National Reproductive Health Policy 2022-2032* Nairobi.

¹³¹ National Reproductive Health Strategy 2014-2018, 12, at <http://origin.searo.who.int/maldives/mediacentre/nrhs-2014-2018.pdf> (accessed 13/08/2020).

¹³² Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

¹³³ Pharmacy and Poisons Board (2022) *Guidelines for Registration of Medical Devices including In-vitro Diagnostics*, Nairobi.

¹³⁴ *Ibid.*

¹³⁵ KNCHR *op.cit.*, at 43.

2.4 Institutional Framework on the Regulation of Sex Lubricants in Kenya

There are a number of institutions that have derived their mandate from the statutes that discussed above and are key in the regulation of sex lubricants in Kenya. The most important institution with relation to sex lubricants is the Kenya Bureau of Standards (KEBS).

KEBS was established by section 3 of the Standards Act, Chapter 496 of the Laws of Kenya. The objectives of the Bureau are among others to promote standardization in industry and commerce, to prepare, frame, modify or amend specifications and codes of practice and to assist in the production of quality goods.

It is one of the 165 members of the International Standards Organization (ISO),¹³⁶ which is an independent, non-governmental international organization that develops voluntary, consensus-based, market relevant International Standards which support innovation and provide solutions to global challenges.¹³⁷

KEBS is therefore an integral institution in the regulation and standardization of sex lubricants in ensuring that the sex lubricants entering the market are of high quality and are safe to use by their consumers. Yet another institution that is critical in the regulation of sex lubricants for safety in Kenya is the the Consumer Federation of Kenya (COFEK) which was registered in 2010. The Federation defines itself as Kenya's independent, self-funded, multi-sectorial, non-political and apex non-profit. It is committed to consumer protection, education, research, consultancy, litigation, anti-counterfeits campaign and business rating on consumerism and customer-care issues.¹³⁸ It is expected to achieve this through defending, promoting, developing and pursuing consumer rights as under Article 46 of the Constitution, the Consumer Protection Act, 2012 and the Competition Act, 2010.

The Federation is therefore important as it ensures that consumers, users of sex lubricants included, use products that are safe for their health and therefore protect their reproductive health rights.

¹³⁶ International Organization for Standardization (2020) "About Us," at <https://www.iso.org/about-us.html> (accessed on 21/8/2020).

¹³⁷ *Ibid.*

¹³⁸ Consumers Federation of Kenya (2020) "About Us," at <http://www.cofek.co.ke/index.php/who-we-are> (accessed on 20/8/2020).

Finally, the Kenya Medical Supplies Authority (KEMSA) is a state corporation under the Ministry of Health (MoH). It is established under section 3 of the Kenya Medical Supplies Authority Act, 2013. The function of KEMSA is among others to procure and distribute medical supplies for prescribed public health programs.¹³⁹ Through its website, KEMSA claims that it not only issues tenders for the supply and delivery of sex lubricants but it also delivers these devices to health facilities in Kenya.¹⁴⁰ Given that deliveries done by KEMSA are of a high standard and quality, it is arguable that the Authority is important in the regulation of sex lubricants in Kenya.

2.5 Regional and International Framework on the Regulation of Sex Lubricants

There are a number of regional and international human rights instruments that guarantee the right to sexual and reproductive healthcare.

2.5.1 Regional Framework on the Regulation of Sex Lubricants

At the regional level, the African Charter on Human and Peoples' Rights ACHPR (Banjul Charter) recognizes the general health of individuals by stating that every individual shall have the right to enjoy the best attainable state of physical and mental health.¹⁴¹ It does not specifically recognize sexual and reproductive health rights of individuals.

The Maputo Protocol to the Banjul Charter has an entire article dedicated to health and reproductive rights.¹⁴² It states that state parties have the obligation to ensure that the right to health of women including sexual and reproductive health is respected and promoted. The right extends to areas such as fertility, family planning, contraception and information regarding their health status. The state parties also have an obligation to take all appropriate measures to provide adequate, affordable and accessible health services to women especially those in the rural areas. The Protocol similarly does not expressly mention the regulation of sex lubricants.

¹³⁹ Kenya Medical Supplies Authority Act 2013, s4(1)(a).

¹⁴⁰ Kenya Medical Supplies Authority (2020) "Distribution," at <https://www.kemsa.co.ke/distribution/> (accessed on 20/8/2020).

¹⁴¹ African Charter on Human and Peoples' Rights (Banjul Charter) 1981, article 16.

¹⁴² Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (Maputo Protocol) 2003, article 14.

In September 1994, the International Conference on Population and Development (ICPD)¹⁴³ indicated that Sexual and Reproductive Health Rights (SRHRs) are rights that embrace certain human rights already recognized in various national laws, international human rights documents and other relevant United Nations consensus documents. The ICPD indicated that these rights rest on the recognition of the basic right of all couples and individuals to the right to attain the highest standard of sexual and reproductive health. It also included the right of all to make decisions concerning reproduction free of discrimination, coercion and violence as expressed in a variety of human rights documents.¹⁴⁴

The ICPD further elaborated that reproductive health is a state of complete physical, mental and social well-being. It added that reproductive health implies that people are able to have a satisfying and safe sex life.¹⁴⁵

One of the ways of achieving a satisfying sex life is through the use of sex lubricants. Therefore, it is important to have lubricants in the market that are not only safe for use but also readily available and effective when used.

Years later in 2006, the African Union Commission (AUC) came up with a continental policy framework on sexual and reproductive health and rights. Taking into consideration the resolutions that arose from the International Conference on Population and Development (ICPD), the Executive Council of the AU Commission came up with several decisions.

One of them is to recognize the role of sexual and reproductive health and rights in the attainment of Millennium Development Goals (MDGs) and the ICPD goals. The Millennium Development Goals (MDGs) are eight (8) goals that United Nations (UN) Member States agreed to try to achieve by the year 2015.¹⁴⁶ It is important to note that the MDGs have now

¹⁴³ This Conference was held in Cairo, Egypt. The United Nations Population Fund (UNPF) termed it as the largest intergovernmental conference on population and development ever held with 179 governments participating, Kenya included.

¹⁴⁴ Report of the International Conference on Population and Development, Cairo, 5-13 September 1994, UN Doc. A/CONF.171/13/Rev. 1(1994)

¹⁴⁵ *Ibid.*

¹⁴⁶ World Health Organization (2018) "Millenium Development Goals (MDGs)" at <https://www.who.int/news-room/fact-sheets/detail/millennium-development-goals> (mdgs#:~:text=The%20United%20Nations%20Millennium%20Declaration,are%20derived%20from%20this%20Declaration. (accessed 19/07/2022).

been superseded by Sustainable Development Goals (SDGs). Sexual and reproductive health care is safeguarded by SDG 3 on good health and well-being.¹⁴⁷

Another decision is to urge member states to mainstream Sexual and Reproductive Health (SRH) in their national health programmes by developing linkages between SRH, HIV/AIDS and other primary health care programmes and to draw inspiration from the Continental's Policy Framework.¹⁴⁸

It should be noted that reservations were entered by the delegations of Djibouti, Egypt, Libya, Somalia and the Sudan.

With regard to consumer protection, there is no regional instrument that governs consumer protection. However, there is a Model Law for Consumer Protection in Africa whose objective is among others, to assist countries in establishing adequate protection for their population as consumers.¹⁴⁹ The model law encourages the enactment of appropriate legislation by African Governments to implement universally applicable aspects of the Model Law as well as the adoption of consumer protection principles by consumer organizations across Africa.¹⁵⁰ The Model Law covers various areas, including consumer protection law, anti-trust and anti-dumping laws.¹⁵¹ The government of Kenya as well as those of South Africa and Nigeria covered in Chapter 3 of this thesis have all promulgated laws related to consumer protection, anti-trust, and anti-dumping in keeping with the model law.

2.5.2 International Framework on the Regulation of Sex Lubricants

At the international front, the Convention on the Elimination of all Discrimination Against Women (CEDAW) recognizes reproductive health rights.¹⁵² The Convention insists in numerous articles that state parties should take all appropriate measures to ensure that women have the right to access to adequate health care facilities and information especially with regard

¹⁴⁷ United Nations (2021) "Sustainable development goals: Goal 3: Ensure healthy lives and promote well-being for all at all ages" at <https://www.un.org/sustainabledevelopment/health/> (accessed 20/10/2021).

¹⁴⁸ African Union Commission (2006) *Sexual and Reproductive Health and Rights Continental Policy Framework*, Botswana.

¹⁴⁹ United Nations (1976) "Consumer protection for Africa: report of the Africa Conference on Consumer Protection, Harare, Zimbabwe, 28 April-2 May 1996" at <https://digitallibrary.un.org/record/692521?ln=en> (accessed 29/11/2023).

¹⁵⁰ *Ibid.*

¹⁵¹ *Ibid.*

¹⁵² Convention on the Elimination of all Discrimination Against Women 1979, articles 11, 12, 14 and 16(1)(e).

to family planning.¹⁵³ It also requires the elimination of all forms of discrimination when it comes to health matters.

The Universal Declaration of Human Rights (UDHR) is yet another international legal instrument that recognizes reproductive health rights.¹⁵⁴ Articles 2 and 25 of UDHR indicate that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including medical care among other rights.

Other international instruments that recognize sexual and reproductive health rights include the International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966 at articles 2 and 12, the International Covenant on Civil and Political Rights (ICCPR), 1966 and the Convention on the Rights of Persons with Disabilities (CRPD), 2006 among others.

With regard to consumer protection, there is no international instrument that governs consumer protections so consumer protection concerns are catered for via either constitutional or statute law of each nation. However, the UN has in place guidelines whose objective is among others to assist countries in achieving or maintaining adequate protection for their population as consumers.¹⁵⁵ The guidelines also stipulate that Member States 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. The guidelines further state that in so doing, Member States should take special account of the work and recommendations of the WHO on pharmaceuticals.¹⁵⁶

The International Consumer Protection and Enforcement Network (ICPEN) is a global network of consumer protection authorities although still fragmented, whose main aim is to encourage practical action against cross-border marketing misconduct by traders.¹⁵⁷ Kenya has been a

¹⁵³ *Ibid*

¹⁵⁴ Universal Declaration of Human Rights, 1948.

¹⁵⁵ United Nations (2016) “Guidelines for consumer protection” at https://unctad.org/system/files/official-document/ditccplpmisc2016d1_en.pdf (accessed 27/11/2023).

¹⁵⁶ *Ibid*.

¹⁵⁷ International Consumer Protection and Enforcement Network (2023) “Who we are” at <https://icpen.org/who-we-are> (accessed 28/11/2023).

member of the Network since 2016. Users of sex lubricants can therefore accrue some rights and/or remedies through this Network.

Access to information which is critical for users of sex lubricants, is safeguarded under Article 19 of the UDHR which in part provides that everyone has the right to seek, receive and impart information and ideas through any media and regardless of frontiers. The right is also recognized under Article 19 of the ICCPR but further states that the right might be restricted only as provided by law and where necessary in instances where there is a need to respect the rights and reputations of others and for the protection of national security or of public order, public health or morals.

2.6 Gaps in the Legal Framework on Regulation of Sex Lubricants

This Chapter 2 has analyzed the legal framework on the regulation of sex lubricants both nationally and internationally. It is evident that majority of the laws and regulations provide for the sexual and reproductive health rights of individuals. Mention of the regulation of sexual lubricants is however scanty. In fact, none of the statutes discussed have expressly discussed the regulation of sex lubricants, defined them, let alone mention them. This thesis therefore relies on the FDA's categorization of sex lubricants as medical devices and the definition of medical devices in section 2 of the Pharmacy and Poisons Act.

This situation is not desirable as the health and safety of users of sex lubricants might be jeopardized due to a lack of proper regulation in the sector. This thesis therefore urges Parliament to enact law that will regulate these and other related devices.

2.7 Conclusion on the Legal Framework on Regulation of Sex Lubricants

This Chapter argues that the various statutes concerning sexual and reproductive health care do not provide clearly and effectively for the regulation of sex lubricants especially in Kenya.

This Chapter addressed the first research objective which was to critically analyze the current national and international legal frameworks and regulations pertaining to sex lubricants. It sought to answer the second research question which is what is the current national and international legal frameworks and regulations on sex lubricants in Kenya?

From the analysis of the current legal frameworks, this chapter finds that there are inadequate laws and regulations that govern the regulation of sex lubricants. Majority of the laws discussed acknowledge that sexual and reproductive health is a human right. They also recognize the right to family planning services, abortion services and maternal health services to the exclusion of accessing health devices such as sex lubricants.

This Chapter therefore recommends the enactment of laws and regulations that clearly and effectively provide for the regulation of sex lubricants.

In the next Chapter, the thesis will discuss the safety concerns in regulating sex lubricants in Kenya.¹⁵⁸

¹⁵⁸ Cf Chapter 3 of this LLM Research Project Paper.

CHAPTER 3

THE SAFETY CONCERNS IN REGULATING SEX LUBRICANTS IN KENYA

3.1 Introduction to the safety concerns in regulating sex lubricants in Kenya

The overarching research question and argument of this Chapter 3 is that there are inadequate safety mechanisms with regard to the regulation of sex lubricants in Kenya.¹⁵⁹

This Chapter 3 addresses the second research objective which is to address the safety concerns arising from the limitations on the legal frameworks and regulations on sex lubricants. It also seeks to answer the second research question which is what safety concerns arise from the limitations of the legal frameworks pertaining to sex lubricants?

The Chapter then discusses Smugel, a water based lubricant manufactured in Kenya. It will study its use and safety for users in Kenya.

Sex lubricants are products that are applied to the condom, vagina, penis or rectum to improve lubrication, moistening and comfort during intercourse.¹⁶⁰ Some are pre-applied to the condom during manufacturing. These are referred to as condom lubricants. Others are packaged separately in bottles or tubes and are referred to as personal or additional lubricants.¹⁶¹ There are also lubricants used for medical purposes. These are referred to as patient lubricants. They are used to lubricate a body orifice to facilitate the entry of a diagnostic or therapeutic device.¹⁶² As previously stated, this study focusses on the regulation of condom and personal/additional lubricants.

¹⁵⁹ Ben Sihanya (2023) Sihanya Mentoring Guidelines on LLM Thesis Proposal, Innovative Lawyering and Sihanya Mentoring, Nairobi & Siaya..

¹⁶⁰ World Health Organization (2012) *Use and procurement of additional lubricants for male and female condoms:* WHO/UNFPA/FHI360, Advisory note, Switzerland at https://apps.who.int/iris/bitstream/handle/10665/76580/WHO_RHR_12.33_eng.pdf;jsessionid=ED748CBFD3DE69897893193C82780ACE?sequence=1 (accessed 13/05/2020).

¹⁶¹ Lauren Harvey (2016) *Classification of Silicone-Based Personal and Condom Lubricants Using DART-TOFMS*, Masters Thesis, University of Central Florida.

¹⁶² Electronic Code of Federal Regulations (2020), at https://www.ecfr.gov/cgi-bin/text-idx?SID=9c83e44dfb9af1f37b84f82df08adfa7&mc=true&node=se21.8.880_16375&rgn=div8 (accessed 08/05/2020).

As has been previously discussed¹⁶³, sex lubricants are commonly used by adults engaging in sexual intercourse but more so by men who have sex with men (MSM), sex workers¹⁶⁴ and postmenopausal women.¹⁶⁵

Other products such as petroleum jelly, saliva, baby oils, lotions and creams are also widely used to minimize pain during sex or to enhance sexual pleasure.¹⁶⁶ These products are commonly used especially in low income households and developing states since users of these products cannot afford lubricants.¹⁶⁷ It is however unknown whether the use of these products for lubrication during sex affects the sexual health of its users.¹⁶⁸

Given that sex lubricants when used come into contact with the mucous membranes of the female and male primary sexual organs,¹⁶⁹ are absorbed in the body and can enter the bloodstream, these products should undergo rigorous regulations to ensure that consumers of these devices access quality, safe and efficient products for their sexual and reproductive well-being. Further, the formulations and ingredients used in the manufacturing of lubricants should be effective to relieve discomfort associated with vaginal dryness and to be physiologically similar to natural vaginal secretions with respect to osmolality and pH.¹⁷⁰

In Kenya, little is known about the actual safety of lubricants themselves as there are limited studies on the safety of these products. In fact limited data exists on the effect sex lubricants have when used by consumers on the rectal mucosa or the female genital tract. It is unclear whether any particular type or brand of lubricant might increase, decrease or have no effect on

¹⁶³ Cf. Chapter 2 of this LLM Research Project Paper.

¹⁶⁴ WHO (2012) *op.cit* at 135.

¹⁶⁵ Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) "A Comparative Study of Smugel and KY Jelly Vaginal Lubricating Gels," *Journal of Reproduction & Contraception*.

¹⁶⁶ Nicholas Muraguri, Marleen Temmerman and Scott Geibel (2012) "A decade of research involving men who have sex with men in Africa: Current knowledge and future directions," 9 *Journal of Social Aspects of HIV/AIDS Research Alliance*.

¹⁶⁷ Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

¹⁶⁸ Jael Obiero (2014) *Development of a vaginal microbicide contraceptive gel (UniPron) for the prevention of sexually transmitted infections and unwanted pregnancies*, PhD Thesis, University of Nairobi.

¹⁶⁹ Bart Desmedt (2019) "Consumer protection provided by the European medical device and cosmetic legislation for condoms and lubricants" *Regulatory Toxicology and Pharmacology Journal* 106-112.

¹⁷⁰ WHO (2012) *op.cit* at 141. See also United Nations Population Fund (2022) "Safe Lubricants for All - Procurement Specifications for Lubricants Used with Male and Female Condoms (Technical Brief)" at <https://www.unfpa.org/publications/safe-lubricants-all-procurement-specifications-lubricants-used-male-and-female-condoms> (accessed 12/07/2023).

acquiring HIV and/or STIs. Since no conclusions can be made, obtaining data on the relative safety of products used as sexual lubricants is incredibly important. This information could be used to promote use of safer lubricants, while discouraging use of lubricants that are less safe.

As extensively discussed in Chapter 2 of this study, Kenyan laws and regulations do not explicitly classify sex lubricants as medical devices.¹⁷¹ The Pharmacy and Poisons Board (PPB) pursuant to the Pharmacy and Poisons Act however regulates medical devices.¹⁷² The PPB classifies medical devices according to risk as follows: Class A low risk, Class B- low to moderate risk, Class C – moderate to high risk and finally Class D- high risk.¹⁷³ The PPB guidelines for registration of medical devices however do not expressly mention sex lubricants.

The Kenya Bureau of Standards (KEBS) considers sex lubricants as medical devices and even has a guideline for inspection of imported medical devices.¹⁷⁴

This study being exploratory in nature therefore heavily relies on medical device regulatory mechanisms used by agencies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA)¹⁷⁵ and guidelines from the World Health Organization (WHO) and the United Nations Population Fund (UNFPA).

This Chapter therefore analyzes the safety concerns arising from the use of sex lubricants arising from their regulation in international markets as well as the limited regulatory controls in the country.

3.2 Safety concerns arising from the use of sex lubricants in Kenya

There are a variety of safety concerns that arise from the use of sex lubricants. Some of them are as a result of their classification, the components found in them and the variation of their pH values in comparison with the pH values of the genitals of individuals using them.

¹⁷¹ Cf. Chapter 2 of this LLM Research Project Paper.

¹⁷² Section 2 Chapter 244 the Laws of Kenya.

¹⁷³ Pharmacy and Poisons Board (2022) “Guidelines for registration of medical devices including in-vitro diagnostics” at <https://web.pharmacyboardkenya.org/download/guidelines-for-registration-of-medical-devices-including-in-vitro-diagnostics/?wpdmdl=6656&refresh=6409b46a9bc591678357610> (accessed 31/03/2023).

¹⁷⁴ Kenya Bureau of Standards (2017) “Inspection of imported medical devices, food supplements, medical cosmetics, herbal products and other borderline products” at https://www.kebs.org/images/pdf/new/Inspection_Guidelines_-_Medical_devices.pdf (accessed 31/03/2023).

¹⁷⁵ Cf. Chapter 2 of this LLM Research Project Paper.

3.2.1 Safety concerns arising from the different types of sex lubricants in the market.

Sex lubricants are classified based on the composition of the ingredients used to manufacture them. There are water based lubricants, silicone-based and oil-based sex lubricants.¹⁷⁶

Research has shown that oil-based sex lubricants degrade latex (used to manufacture condoms) due to the fact that they contain minerals. This composition makes condoms more likely to break.¹⁷⁷ Studies have also indicated that adding oil-based lubricants to condoms increased the risk of condom breakage or slippage.¹⁷⁸ As a result, oil based sex lubricants are not preferred for use and readily available.

Silicone based sex lubricants on the other hand are favourable to use according to studies. However, their use has been associated with slightly more genital symptoms in comparison with water based sex lubricants.¹⁷⁹

Water based sex lubricants are easy to produce and hence affordable.¹⁸⁰ They are also generally compatible with condoms and have high user acceptability. Some studies have however indicated that some components of water-based lubricants may induce changes to the vaginal environment.¹⁸¹ These changes can leave the vagina irritated and may ultimately lead to toxic effects and even enhance the transmission of sexually transmitted infections (STIs) and diseases such as Human Immunodeficiency Virus (HIV) which affect the general health of users as well as their reproductive health.¹⁸²

¹⁷⁶ WHO, *op. cit.*, at 2.

¹⁷⁷ Cf. Obiero “*Development of a vaginal microbicide contraceptive gel (UniPron) for the prevention of sexually transmitted infections and unwanted pregnancies.*”

¹⁷⁸ Obiero, *ibid.*

¹⁷⁹ Debra Herbenick, Michael Reece, Devon Hensel et.al. (2010) “Association of lubricant use with women’s sexual pleasure, sexual satisfaction, and genital symptoms: A prospective daily diary study” at <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1743-6109.2010.02067.x> (accessed 28/09/2020).

¹⁸⁰ Ana Raquel Cunha, Rita M. Machado, Ana Palmeira-de-Oliveira et.al (2014) “Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective” at <https://pubmed.ncbi.nlm.nih.gov/25247884/> (accessed 26/09/2020).

¹⁸¹ Cunha, Machado, de-Oliveira, *ibid.* See also section 3.2.3 of this LLM Research Project Paper.

¹⁸² Ellen Wilkinson, Melissa Herbst-Kralovetz et.al (2019) “Personal and Clinical Vaginal Lubricants: Impact on Local Vaginal Microenvironment and Implications for Epithelial Cell Host Response and Barrier Function” 220 *The Journal of Infectious Diseases* 2009-2018 at <https://academic.oup.com/jid/article/220/12/2009/5563809> (accessed 12/07/2023).

3.2.2 Safety concerns arising from the classification of sex lubricants

As has been discussed in the previous chapter, the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as well as most regulatory bodies around the world categorize sex lubricants as either Class I or Class II medical devices depending on the use or formula of the lubricant.¹⁸³

Testing of medical devices for safety is conducted only on animals such as rabbits by the FDA.¹⁸⁴ Wilkinson in her article states that the animal model systems do not accurately reflect the human vaginal microenvironment.¹⁸⁵ This raises a safety concern on the accuracy of the findings of these studies when sex lubricants are used by humans.

Yet another safety concern arising is that products classified as medical devices need not disclose the ingredients used to manufacture them on their packaging.¹⁸⁶ This poses risks such as adverse reactions to certain ingredients when used by some people. Additionally, it goes against the principle of providing consumer awareness and information on consumers of such products contrary to the provisions of the Consumer Protection Act¹⁸⁷ as well as Article 46 of the Constitution of Kenya.

Class I medical devices pose a low to moderate risk to users of such devices while Class II medical devices pose a moderate to high risk to their users. This difference in risk determines the regulatory controls medical devices in either category are subjected to. Majority of Class I medical devices in the US are exempt from the FDA's requirements for premarket notification

¹⁸³ Cf. FDA "Product classification". See also UNFPA (2016) "Global Consultation on Personal Lubricants." The Medical Devices Agency (MDA), an agency of the Department of Health in the UK also categorizes personal lubricants as medical devices.

¹⁸⁴ Cf Ellen Wilkinson, Melissa Herbst-Kralovetz et.al (2019) "Personal and Clinical Vaginal Lubricants: Impact on Local Vaginal Microenvironment and Implications for Epithelial Cell Host Response and Barrier Function."

¹⁸⁵ *Ibid.*

¹⁸⁶ Nicole Weendee (2014) "A question for women's health: Chemicals in feminine hygiene products and personal lubricants" *Environmental Health Perspectives* A70-A75 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948026/> (accessed 26/09/2020).

¹⁸⁷ S 4(e) of the Act.

and premarket approvals.¹⁸⁸ Most vaginally applied lubricants intended for a non-medical purpose such as sexual comfort/pleasure fall into this categorization.¹⁸⁹

Class II medical devices on the other hand undergo more rigorous controls in comparison with Class I medical devices. Most of these devices require premarket notifications from the FDA as well as requirements for post-market surveillance and special labeling requirements.¹⁹⁰

Owing to the stricter regulations Class II medical devices undergo, this study posits that all sex lubricants categorized as Class I medical devices should instead be categorized as Class II medical devices to protect the consumers of such products.

Alarming, some personal lubricants are promoted as moisturizers or genital cleansing products and are considered as cosmetics.¹⁹¹ Cosmetics can be defined as any preparation intended for placing in contact with various external parts of the human body (epidermis, hair, nails, or lips) or with the teeth and mucous membranes of the oral cavity with a view to exclusively or principally cleaning them, perfuming them, or protecting them in order to keep them in good condition, change their appearance or correct body odours.¹⁹² They include any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes.¹⁹³

Generally, regulation of cosmetics is less rigorous as compared to the regulation of medical devices. In the USA for example, cosmetics are exempt from FDA premarket approval.¹⁹⁴ In fact, the FDA has no authority under the Food, Drug and Cosmetics Act to recall cosmetics

¹⁸⁸ Food and Drug Administration (2020) “Overview of device regulation” at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation> (accessed 10/3/2023).

¹⁸⁹ Health Sciences Authority (2021) “Medical devices product classification guide” <https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/medical-devices-product-classification-guide.pdf> (accessed 10/03/2023).

¹⁹⁰ US Food, Drug and Cosmetics Act, s 510(k).

¹⁹¹ Scott Geibel (2013) “Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa” *Journal of the International AIDS Society* 2-3.

¹⁹² Kenya Bureau of Standards (2021) “Cosmetics – General requirements for safety of cosmetic products-specification” at https://members.wto.org/crnattachments/2021/TBT/KEN/21_2237_00_e.pdf (accessed 22/02/2023)

¹⁹³ Food, Drugs and Chemical Substances Act, Chapter 254 Laws of Kenya, s 2.

¹⁹⁴ Food, Drug and Cosmetics Act of the United States,

already in the market.¹⁹⁵ Recalling of cosmetics are voluntary actions taken by manufactures or distributors of the cosmetics.¹⁹⁶ In Kenya, the regulation of cosmetics has been wanting. Banned cosmetic products, with links to cancer and other adverse health effects, have been reported to be circulating in the Kenyan market.¹⁹⁷ This is an alarming situation considering that the PPB and KEBS had years prior, issued guidelines on the inspection of among other things, medical cosmetics under the Pre-Export Verification of Conformity (PVoC) to Standards programme.¹⁹⁸ The programme, which is still running, intends to ensure that only quality goods gain entry into the country in conformity with the Standards Act¹⁹⁹ as well as the Verification of Conformity to Kenya Standards of Imports Order, 2005.²⁰⁰

Recently, KEBS reviewed the Kenya Standards guiding cosmetics in Kenya. Cosmetics are currently subject to the Kenyan Standard KS 2937:2021.²⁰¹ This standard covers parameters to be observed in the manufacturing of cosmetics such as requirements on ingredients, thermal stability, pH ranges, microbiological limits, packaging, labeling and sampling.²⁰² It is commendable that the PPB and KEBS continuously review and update guidelines on the regulation of cosmetics however it has been argued that these regulatory controls are not sufficient.²⁰³

From the foregoing, it is apparent that having sex lubricants in the market that are considered as cosmetics poses health risks to consumers of these products as the regulatory mechanisms

¹⁹⁵ Food and Drug Administration (2022) “FDA recall policy for cosmetics” at <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics> (accessed 22/02/2023).

¹⁹⁶ Food and Drug Administration (2022) “FDA authority over cosmetics: How cosmetics are not FDA-approved, but are FDA-regulated” at <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#:~:text=The%20two%20most%20important%20laws,laws%20are%20enacted%20by%20Congress> (accessed 22/02/2023).

¹⁹⁷ Betty Muindi (2019) “Banned substances abound in Kenyan cosmetics market” *People Daily* at <https://www.pd.co.ke/news/banned-substances-abound-in-kenyan-cosmetics-market-540/> (accessed 17/02/2023)

¹⁹⁸ Aggrey Omboki (2017) “Medical kits, cosmetics to face scrutiny” *Daily Nation* at <https://nation.africa/kenya/news/medical-kits-cosmetics-to-face-scrutiny-446710> (accessed 17/02/2023).

¹⁹⁹ Cap 496, Laws of Kenya.

²⁰⁰ Legal Notice No. 78 of 15th July 2005.

²⁰¹ Cf. KEBS “Cosmetics – General requirements for safety of cosmetic products- specification”.

²⁰² *Ibid.*

²⁰³ Cathy Mputhia (2021) “Get tighter laws to weave beauty industry growth” *Business Daily* at <https://www.businessdailyafrica.com/bd/lifestyle/fashion/get-tighter-laws-to-weave-beauty-industry-growth-3853230> (accessed 23/02/2023).

of cosmetics are less rigorous than those subjected to medical devices and pharmaceutical products.

In 2003, the Food and Drug Administration (FDA), a United States federal agency of the department of health and human services, reviewed the safety and efficacy of sex lubricants. In the review, they clarified that sex lubricants claiming to decrease pain, enhance sexual pleasure or contain spermicide would be categorized as drugs since they are related to easing discomfort or alleviating a condition which is more or less the mitigation or treatment of disease.²⁰⁴

Given the less stringent regulatory controls cosmetics are subjected to and in response to the FDA review²⁰⁵, Geibel in his article states that the categorization of sex lubricants as drugs by the FDA was not welcomed by some lubricant manufacturers and their representatives who argued that the intended use of lubricants is for cosmetic purposes as opposed to treating disease. This opposition stemmed from the fact that having lubricants classified as drugs by the FDA could add a further regulatory and financial burden upon lubricant manufacturers by requiring them to test lubricants for safety.²⁰⁶

This reluctance from a section of manufacturers to classify sex lubricants as drugs may affect the users of these products due to the lack of intense regulation of sex lubricants and cosmetic products as opposed to the process through which medical drugs are regulated. The effect of this is having sex lubricants in the market that have not undergone extensive testing and therefore, are of a low quality and standard exposing the consumers of these products to the risk of contracting STIs and unwanted pregnancies as a result of condom breakages.

For Kenya, this classification issue affects constitutional rights, including the individual's right to attain the highest standard of health as guaranteed under Article 43. Classification impacts the presence or absence of regulatory assessment of sex lubricants for the safety of consumers pre-product launch, the effect of component concentrations and PH value on user genitals and overall health. Classification also affects consumer rights protected under Article 46 with

²⁰⁴ Cf Food and Drug Administration (2003) "Over-the-counter drug products; safety and efficacy review."

²⁰⁵ *Ibid.*

²⁰⁶ Cf. Geibel (2013) "Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa" at 17.

regard to the right to quality goods, the right to compensation in case of injury and the right to access information as protected under Article 35 as relates to ingredients of sex lubricants and how to best use the product. There is a currently a lacuna in Kenya with regard to classification of sex lubricants.

From the foregoing discussion on classification regimes abroad, the classification of sex lubricants in Kenya as cosmetics would result in products not being subject to any regulatory registration or conformity assessments prior to market release, as well as products not being subject to regulatory labelling requirements for the disclosure of ingredients that may jeopardize consumer safety. Lack of conformity assessment means there will be no mechanism to ensure WHO recommendations with regard to component concentrations and recommended pH values are implemented. Also, for cosmetic products, in case of any product safety issue being discovered post-market launch, then product recall is at the option of the manufacturer- there is no central regulator who can mandate product recall even where a consumer safety issue is confirmed or ascertained. This negatively impacts the right to reproductive health guaranteed under Article 43 and consumer rights to quality goods as guaranteed under Article 46 of the Constitution.

Classification of sex lubricants in Kenya as a class I medical device would only provide limited protection of the right to reproductive health as protected in Article 43 of the Constitution. The limited protection would be because, in case of a discovery of safety issues post-product launch, the relevant regulator would be able to mandate a product recall from a consumer protection perspective as guaranteed under Article 46 of the Constitution. However, such classification would not enable the regulator to undertake any conformity testing for compatibility of the sex lubricants with contraceptives such as condoms and this can endanger consumer health if product use exposes them to condom breakage or slippage and consequently unwanted pregnancies, HIV and other STIs, limiting their ability to attain the highest standard of health as guaranteed under Article 43 of the Constitution.

Classification of sex lubricants in Kenya as class II medical devices (moderate to high risk devices) is essential for lubricants that are intended to be used on their own or in conjunction

with condoms, as the regulator would be able to assess the product for safety and biocompatibility with human skin, compatibility and safety of use with the relevant condom material as well as cater for the osmolality and pH issues in keeping with WHO recommendations and relevant findings from scientific research. This would help protect the right to reproductive health as protected in Article 43 of the Constitution, and also, in case of any safety issue, the relevant regulator would have the power to recall product protection consumers to protect consumer rights as guaranteed under Article 46 of the Constitution. Additionally, all relevant information would be disclosed to the consumer via labelling requirements to enable the enjoyment of rights guaranteed under Article 35 of the Constitution.

3.2.3 Safety concerns arising from the components of sex lubricants

Most sex lubricants contain ingredients that may be harmful to users of sex lubricants.²⁰⁷ Numerous studies have indicated that most water based lubricants contain nonoxynol-9 (N-9), an organic compound used as a vaginal spermicide.²⁰⁸ The compound is widely used as it is relatively cheap and has been advocated as preventing some sexually transmitted infections.²⁰⁹

Prior to the year 2000, N-9 was one of the components in several water-based lubricants marketed specifically to MSM for use with condoms.²¹⁰ This was due to the fact that laboratory tests conducted in the 1970s and 1980s in the USA showed that the compound could inactivate organisms causing gonorrhoea, chlamydial infections as well as other STIs including HIV.²¹¹ However, over the years numerous studies have shown that the component has been linked to directly enhance the acquisition of HIV in some of its users.²¹² The WHO in its 2001 summary

²⁰⁷ Lauren K Wolf (2012) “Studies raise questions about safety of personal products,” at <https://cen.acs.org/articles/90/i50/Studies-Raise-Questions-Safety-Personal.html>(accessed 18/05/2020).

²⁰⁸ Cf Michael Stafford, Helen Ward, Adrienne Falanagan et.al (1998) “Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects,” *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*.

²⁰⁹ Stafford, Ward and Falanagan *ibid*.

²¹⁰ Stafford, Ward and Falanagan *ibid*.

²¹¹ World Health Organization (2002) “Nonoxynol-9 ineffective in preventing HIV infection” <https://www.who.int/news/item/28-06-2002-nonoxynol-9-ineffective-in-preventing-hiv-infection>. (accessed 20/02/2023)

²¹² Cf. Stafford, Ward and Falanagan “Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects,” *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*.

report,²¹³ a collaborative effort between the WHO Department of Reproductive Health and Research and the CONRAD program of the USA, dissuaded states on the use of N-9.

In addition to increasing the risk of HIV infection in women, the WHO report concluded that lubricated condoms containing N-9 did not necessarily protect against pregnancy or sexually transmitted infections than condoms lubricated with silicone. Further, the report recommended that since N-9 may cause adverse effects on its users, lubricated condoms containing the compound should no longer be promoted.²¹⁴ Additionally, N-9 has been shown to damage the rectal epithelium, which is the outermost lining of the rectum.²¹⁵ As a result, this compound is no longer recommended for use in sex.

Due to these safety concerns, many manufacturers have since discontinued marketing N-9-containing lubricants to MSM.²¹⁶ However, a further scrutiny of water based lubricants may show that the N-9 compound is still present in them. The WHO report recommends that N-9 lubricated condoms should no longer be promoted. This stance is based on the fact that no published scientific evidence indicates that such condoms provide any additional protection against pregnancy or STIs in comparison with condoms lubricated with other products.²¹⁷ This thesis follows the stand taken by the WHO and argues that sex lubricant manufacturers should discontinue using this compound when manufacturing water-based sex lubricants.

²¹³ WHO/CONRAD (2003) “*Technical Consultation on Nonoxynol- 9.*” https://apps.who.int/iris/bitstream/handle/10665/68510/WHO_RHR_03.08.pdf;jsessionid=F8AE1431BBD208ABB6B746D2E5C8BB70?sequence=1 (accessed 28/09/2020) Geneva.

²¹⁴ *Ibid.*

²¹⁵ Stafford, Ward and Falanagan “Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects,” *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* *op.cit* at 187.

²¹⁶ Tim Lane and Herminia Palacio (2006) “Safer-sex methods,” at <http://hivinsite.ucsf.edu/InSite?page=kb-07-02-02> (accessed 27/09/2020).

²¹⁷ Cf. WHO/CONRAD (2003) “*Technical Consultation on Nonoxynol- 9.*”

Furthermore, different animal studies²¹⁸ indicate that water-based lubricants may induce changes to the vaginal environment due to their composition which can lead to toxic effects and, eventually transmission of sexually transmitted infections such as HIV.²¹⁹

Such lubricants contain emollient/humectants such as glycerin and propylene glycol used to maintain the water content of the lubricants.²²⁰ Humectants when applied to the body draw water from the dermis to the upper layer of the skin (the epidermis). Sex lubricants containing large volumes of humectants as one of their ingredients work in the same way, pulling moisture out of the vaginal tissue. Dezzutti explains in her article that hyperosmolar lubricants tend to pull water out of the vaginal epithelium causing the cells to shrink and shrivel.²²¹

Some of these water based lubricants are also hyperosmolar,²²² (their component concentration (osmolality) are higher than the body's cells) and their osmolality values exceed the osmolality values recommended by the WHO.²²³ The WHO recommends that sex lubricants should have osmolalities of not greater than 1,200 mOsm/kg yet the WHO reports that most commercial sex lubricants have osmolalities of between 2000-6000 mOsm/kg.²²⁴ Various animal studies have also indicated that sex lubricants available in international markets such as the well-known K-Y Jelly manufactured by Johnson and Johnson, USA and others such as McKesson Lubricant²²⁵ contain osmolality values above those recommended by the WHO. These high osmolar values negatively affect users of sex lubricants when used over time because they draw water from

²¹⁸ Els Adriaens and Jean Paul Remon (2008) "Mucosal Irritation Potential of Personal Lubricants Relates to Product Osmolality as Detected by the Slug Mucosal Irritation Assay" *Sexual Transmitted Diseases* 512-516 at https://journals.lww.com/stdjournal/Fulltext/2008/05000/Mucosal_Irritation_Potential_of_Personal.16.aspx (accessed 13/07/2023). See also Edward Fuchs, Linda Lee, Michael Torbenson et.al (2007) "Hyperosmolar Sexual Lubricant Causes Epithelial Damage in the Distal Colon: Potential Implication for HIV Transmission" *The Journal of Infectious Diseases* 703-710 at <https://doi.org/10.1186/s12879-021-06512-x> (accessed 13/07/2023).

²¹⁹ Charlene Dezzutti, Elizabeth Brown, Bernard Moncla (2012) "Is wetter better? An evaluation of over-the-counter personal lubricants for safety and anti HIV-1 activity," at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0048328> (accessed 28/09/2020).

²²⁰ Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms*.

²²¹ Cf Charlene Dezzutti, Elizabeth Brown, Bernard Moncla (2012) "Is wetter better? An evaluation of over-the-counter personal lubricants for safety and anti HIV-1 activity".

²²² UNFPA (2022), *op. cit.*, at 12.

²²³ WHO, *op. cit.*, at 1.

²²⁴ Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms*.

²²⁵ Cf Ellen Wilkinson, Pawel Laniewski (et.al.) (2019) Personal and Clinical Vaginal Lubricants: Impact on Local Vaginal Microenvironment and Implications for Epithelial Cell Host Response and Barrier Function.

the epithelial cells in the vagina or rectum, damaging the epithelial barrier of these organs and causing the shedding of the epithelial cells.²²⁶

Further, a study conducted in South Africa determining the osmolality of the available sex lubricants in that market and their potential to cause rectal epithelial damage revealed that about 88% of the lubricants studied were hyperosmolar.²²⁷ The study noted that these products were mainly used by MSM, in the absence of condoms, with the belief that they provide protection from HIV infection by decreasing friction and resultant trauma to the rectal mucosa when used during sex.²²⁸ However, given the fact that hyperosmolar products have been shown to cause epithelial injury, they could have the potential to increase HIV acquisition and transmission among this group.

These safety concerns have been noted by the World Health Organization (WHO). The Organization then collaborated with the United Nations Population Fund (UNFPA) and Family Health International (FHI360) and issued an advisory on the technical requirements of lubricants namely when used in addition to condoms.²²⁹

3.2.4 Safety concerns arising from pH values of sex lubricants in Kenya

It is alarming that studies have indicated that most sex lubricants in the market present pH values outside the ranges recommended by the WHO.²³⁰ A healthy human vagina is acidic with a pH ranging from 3.8 to 4.5.²³¹ In order to avoid changing the pH environment of the vagina, vaginal sex lubricants should ideally have a pH of about 4.5. The WHO also indicates that the pH of the rectum is closer to neutral (pH 7). Ideally rectal lubricants should have a pH of about

²²⁶ Santiago Palacios, Sarah Hood, Temitayo Abakah-Phillips et.al. (2023) “A Randomized Trial on the Effectiveness and Safety of 5 Water-based Personal Lubricants” 20 *The Journal of Sexual Medicine* 498-506 at <https://academic.oup.com/jsm/article/20/4/498/7035572?login=false> (accessed 12/07/2023).

²²⁷ Kevin Rebe, Glenn Swardt (et.al.) (2014) “Sexual lubricants in South Africa may potentially disrupt mucosal surfaces and increase HIV transmission risk among men who have sex with men” *South African Medical Journal* 49-51 at <https://www.ajol.info/index.php/samj/article/view/99850> (accessed 18/07/2023).

²²⁸ *Ibid.*

²²⁹ Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms*.

²³⁰ Cunha, Machado, de-Oliveira (2014) “Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective, *op.cit.*, at 17.

²³¹ Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms*.

5.5 to 7²³². The optimum pH values of sex lubricants as recommended by the WHO should be those with a pH of 7 or less.²³³

Studies have concluded that the pH values of sex lubricants should be compatible with that of the normal vaginal physiology to avoid making changes to the vagina.²³⁴ High vaginal pH can lead to an increase in the risk of bacterial vaginosis (BV) and is supportive of HIV survival.²³⁵ The studies also suggest and recommend that regulatory agencies and manufacturers should re-evaluate sex lubricants and ultimately reformulate them for the benefit of lubricant consumers.²³⁶

3.3 Other concerns arising from the use of sex lubricants in Kenya and Africa

There are other concerns that arise from the use of sex lubricants. Multiple studies conducted in Kenya indicate that MSM largely use sex lubricants during sexual intercourse. However, most of them indicated that the available sex lubricants in the market are beyond their reach due to their high costs.²³⁷

The national AIDS strategic plan powered by the Ministry of Health and the National AIDS Control Council also observed that there are frequent stock outs on condoms and condom-compatible lubricants as development partners and not the Kenyan Government procure and distribute these products.²³⁸ The plan recommends that there is need to formulate policy that ensures comprehensive and consistent procurement, supply and distribution of a number of products, lubricants included, as part of an Essential Drugs List.²³⁹ The plan recommends that these products should be procured and distributed specifically to MSMs and sex workers. The plan notes that there have been recommendations by previous policy documents on making

²³² *Ibid.*

²³³ *Ibid.*

²³⁴ Cf Cunha, Machado, de-Oliveira (2014) “Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective.

²³⁵ Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms.*

²³⁶ Cunha, Machado, de-Oliveira 2014) “Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective, *op.cit.*, at 209.

²³⁷ Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

²³⁸ Ministry of Health (2014) “*Policy analysis and advocacy decision model for services for key populations in Kenya*” at

https://www.healthpolicyproject.com/pubs/744_KenyaMSMDecisionModelReportFORMATTEDfinal.pdf,

Nairobi (accessed 28/09/2020).

²³⁹ *Ibid.*

condoms and sex lubricants available to vulnerable groups of the population and to list them as part of the essential packages.²⁴⁰

These recommendations have not been fully implemented hence the plan recommends that the Government should have a strategy and formulate policy for funding, procurement and distribution of these products.

This thesis therefore recommends that one of the strategies the government can adopt is to encourage and incentivize more drug manufacturers in Kenya to manufacture sex lubricants in a bid to lower their price in the Kenyan market as compared to imported sex lubricants. To this end, it is commendable that the Institute of Primate Research (IPR), a biomedical research institution in Kenya manufactures a water-based and water-soluble lubricant named Smugel.²⁴¹

In Tanzania, the Government banned the import and sale of sex lubricants. The government claimed that these products promote homosexuality as MSM used them and with it a rise in HIV/AIDS and its spread.²⁴² This has left users of these products to resort to using saliva, margarine, herbs, coconut oil, Vaseline and cooking oil,²⁴³ substances that may compromise their safety and adversely affect their health. Stakeholders however noted that sex lubricants are not only used by MSM but also heterosexuals during sex and by women for gynecological exams²⁴⁴ and therefore the ban by the Government would affect more people other than homosexuals.

Ironically, the ban by the Tanzanian Government goes against their own national guidelines for the management of sexually transmitted and reproductive tract infections published in 2007. The guidelines actually encourage users to “use water based lubricants such as glycerine or KY

²⁴⁰ Such policies include the Ministry of Health’s 2010 National Condom Policy and Strategy and the National Guidelines for HIV/STI Programs for Sex Workers (2010).

²⁴¹ Cf Chapter 3.4 of this LLM Research Project Paper.

²⁴² Amy Fallon (2016) “Tanzania has banned lubricants over the belief that it “promotes homosexuality” at <https://www.sbs.com.au/topics/pride/agenda/article/2016/10/07/tanzania-has-banned-lubricants-over-belief-it-promotes-homosexuality> (accessed 25/09/2020).

²⁴³ Fallon, *ibid*.

²⁴⁴ Gift Lukumay, Lucy Mgopa (et.al) (2023) “Community myths and misconceptions about sexual health in Tanzania: Stakeholders’ views from a qualitative study in Dar es Salaam Tanzania” *PLoS ONE* 18(2) at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0264706> (accessed 19/07/2023).

jelly and avoid oil based lubricants.”²⁴⁵ Notwithstanding that this recommendation as per our discussion on the safety concerns of ingredients contained in sex lubricants in Section 3.2.3 of this study is misleading.

Another concern arising from the ban of sex lubricants in Tanzania is that there might be a surge in sexually transmitted infections (STIs) and HIV infections. This is because numerous agencies including UNAIDS have shown that condom and lubricant programming is effective in preventing transmission of HIV especially when these products are used by MSM.²⁴⁶

In South Africa on the other hand, a study conducted by Rebe (et.al.) indicated that the use of sex lubricants in the country particularly by MSM could potentially disrupt the mucosal surfaces of the rectum leading to an increase in the risk of contracting HIV.²⁴⁷ Out of the eight (8) sex lubricants found in the South African market and tested for osmolality, only one had osmolality values lower than the values recommended by the WHO.²⁴⁸ As such Rebe recommends MSM in South Africa to use sex lubricants that are hypo-osmolar in conjunction with condoms.

3.4 Emerging sex lubricants in Kenya

The Institute of Primate Research (IPR) based in the Kenya National Innovation Agency (KENIA) is an ISO certified biomedical research institution. In 2010, the institution introduced Smugel, a water-based and water soluble lubricant for a variety of usage. The lubricant was manufactured by a Kenyan pharmaceutical company as a result of research conducted by the Institute which also doubles up as a WHO designated collaborating centre.²⁴⁹

²⁴⁵ The United Republic of Tanzania, Ministry of Health and Social Welfare (2007) National Guidelines for the Management of Sexually Transmitted and Reproductive Tract Infections at https://www.jica.go.jp/Resource/project/tanzania/001/materials/pdf/sti_01.pdf (accessed 19/07/2023).

²⁴⁶ Cf Michael Stafford, Helen Ward, Adrienne Falanagan et.al (1998) “Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects.”

²⁴⁷ Cf Kevin Rebe, Glenn Swardt (et.al.) (2014) “Sexual lubricants in South Africa may potentially disrupt mucosal surfaces and increase HIV transmission risk among men who have sex with men.”

²⁴⁸ *Ibid.* Cf WHO (2012) *Use and procurement of additional lubricants for male and female condoms.*

²⁴⁹ Sarah Ooko (2017) “New gel to enhance reproductive health” *Business Daily* at <https://www.businessdailyafrica.com/bd/lifestyle/health-fitness/new-gel-to-enhance-reproductive-health-2167790> (accessed 01/03/2023). See also Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) “A comparative study of Smugel and KY Jelly vaginal lubricating gels,” *Journal of Reproduction & Contraception.*

According to the institute, Smugel can be used for personal use for moistening and lubrication and in hospital for surgical instrumentation, lubrication during various procedures in family planning clinics, during deliveries and other medical procedures.²⁵⁰

The Institute has indicated that Smugel does not react with latex condoms and therefore it can be used with condoms without worry. Furthermore, a study compared Smugel to another widely known sex lubricant, KY Jelly. The finding of the study indicated that Smugel did not induce any adverse effects that may facilitate the transmission of STIs and pathogens such as HIV.²⁵¹

On purchasing this product²⁵², this study observed that Smugel contains glycerin as one of its ingredients. As previously discussed in this Chapter,²⁵³ glycerin – a common ingredient in sex lubricants- is a humectant that can draw moisture from the dermis to the epithelium of the vagina or rectum when used during sex leading to the drying and shrinking of vaginal or rectal cells. It is unclear whether the occurrence of glycerin in Smugel causes osmolality values beyond those recommended by the pH as studies on the same are yet to be conducted. It should be noted however that the drug insert contained a contraindication warning of sensitivity to glycerin. This thesis recommends that research should be conducted to obtain these values in order to ensure that the safety of users of Smugel is safeguarded.

The institute has also manufactured Smuscan, an ultrasound gel. To support their efforts, the Government has set aside 4.5 million shillings to develop and market a locally invented HIV killing gel.²⁵⁴ The efforts of the institute are commendable as they have introduced products that are locally available and affordable to majority of people in the country. More manufacturers should therefore strive to manufacture sex lubricants locally in a bid to enhance and improve the sexual and reproductive health of consumers of this product.

²⁵⁰ Institute of Primate Research (2017) “Reproductive health and biology,” at <http://primateresearch.org/567-2/> (accessed 25/09/2020).

²⁵¹ Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) “A comparative study of Smugel and KY Jelly vaginal lubricating gels,” *Journal of Reproduction & Contraception*.

²⁵² The lubricant was purchased in a pharmacy in Nairobi. The drug insert indicated that for each 20g and 50g of the lubricant, it contained 2gms and 5gms of Glycerin BP respectively.

²⁵³ Cf section 3.2.3 of this LLM Research Project Paper.

²⁵⁴ Aggrey Omboki (2019) “Agency gets Sh 4.5 million to develop HIV-killing gel,” *Daily Nation* at <https://nation.africa/kenya/news/agency-gets-sh4-5-million-to-develop-hiv-killing-gel-188158> (accessed 25/09/2020).

Sexual and reproductive health is a fundamental human right²⁵⁵ and therefore it is integral that sex lubricants that are in the market promote the safety of lubricant users.

3.5 Conclusion on the Safety Concerns Arising from Regulating Sex Lubricants in Kenya

This Chapter 3 has analyzed the safety concerns arising from the regulation of sex lubricants. It argues that Kenya lacks adequate safety mechanisms in place that are specific to the regulation of sex lubricants. However, there has been emerging research and innovation headed by the Institute of Primate Research. The Institute through a Kenyan pharmaceutical company manufactured Smugel, a water based lubricant that is used for a variety of uses.²⁵⁶ The lubricant is also said to be compatible with latex condoms.²⁵⁷

This development in the research and manufacture of sex lubricants that are of a high quality and standard is commendable. This thesis argues that the Institute should collaborate with more local pharmaceutical companies to manufacture quality and affordable sex lubricants to users of the products.

The chapter addresses the second research objective which is to address the safety concerns arising from the limitations on the legal frameworks and regulations on sex lubricants. It also answers the second research question which is what safety concerns arise from the limitations of the legal frameworks pertaining to sex lubricants?

From the analysis, it is evident that there are several safety concerns that arise when using sex lubricants. Some of these include the various classification of sex lubricants as either medical devices or cosmetics, the components that constitute sex lubricants and the variation of pH levels of the sex lubricants from that of the genitals.

The next chapter of this thesis will make a comparative analysis with other jurisdictions that have sex lubricant regulations in place and make relevant recommendations that Kenya can adopt.

²⁵⁵ Cf chapter 2 of this LLM Research Project Paper.

²⁵⁶ Cf. Institute of Primate Research (2017) "Reproductive health and biology."

²⁵⁷ Cf. Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) "A comparative study of Smugel and KY Jelly vaginal lubricating gels."

CHAPTER 4

COMPARATIVE STUDY ON THE REGULATION OF SEX LUBRICANTS IN OTHER JURISDICTIONS

4.1 Introduction to the Comparative Study on the Regulation of Sex Lubricants in other Jurisdictions.

In the previous Chapter, this study discussed the various safety concerns arising from the regulation (or lack of) of sex lubricants in Kenya. This Chapter 4 seeks to make a comparative analysis on the regulation of sex lubricants for safety in other jurisdictions. It explores the regulation of sex lubricants in South Africa and Nigeria and makes a comparative analysis with the regulation of these products by international agencies such as the Federal Drug Agency (FDA) of the USA and the European Medicines Agency (EMA) in Europe.

This Chapter addresses the second research objective which is to outline lessons Kenya can learn from the comparative study on how to improve the available laws and regulations pertaining to sex lubricants in Kenya.²⁵⁸

This Chapter also answers the third research question which seeks to find out what lessons Kenya can gain from the comparative study on the regulation of sex lubricants in other jurisdictions with regard to operationalizing Articles 43(1)(a) and 46 of the Constitution, 2010.²⁵⁹

4.2 Regulation of Sex Lubricants for Safety in South Africa

The Kenyan Constitution borrowed many provisions from its South African counterpart and a reading of the two documents establishes this. As a result, the two Constitutions are quite similar in many aspects.

Article 231 of the Constitution of the Republic of South Africa stipulates that international agreements either approved by the National Assembly and the National Council of Provinces or entered into by the national executive are binding on the Republic.²⁶⁰ As a result, South

²⁵⁸ See section 1.3.2 of this LLM Research Project Paper.

²⁵⁹ See section 1.4 of this LLM Research Project Paper.

²⁶⁰ Constitution of the Republic of South Africa, 1996, Article 231.

Africa is party to and has incorporated into domestic law various international human rights instruments that provide for the protection of sexual and reproductive health rights.²⁶¹

The Constitution in its Bill of Rights recognizes the right to healthcare as one of the rights South Africans enjoy.²⁶² Article 27(1) of the Constitution stipulates that everyone has the right to have access to health care services, including reproductive health care. Further, Article 27(2) mandates the state to take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of the right.

The South African Constitution affords other rights to its citizens that are critical in safeguarding their sexual and reproductive health rights such as the right to human dignity, access to information as well as access to courts in resolving any disputes.²⁶³ Article 36 of the Constitution stipulates that these rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.

Apart from sexual and reproductive health rights being safeguarded in the South African Constitution, these rights are also guaranteed and protected through numerous statutes. The National Health Act²⁶⁴ in its definition section defines health services in tandem with the Constitution to include reproductive health care. One of the objectives of the Act is to protect, respect, promote and fulfill the rights of the people of South Africa to the progressive realization of the constitutional right of access to health care services, including reproductive health care.²⁶⁵

The consumer rights of users of sex lubricants in South Africa are protected under the Consumer Protection Act, 2008.²⁶⁶ In its Preamble, the Act stipulates that its aim is among other things to promote and protect the economic interests of consumers, improve access to,

²⁶¹ South Africa is a party to CEDAW, the ICCPR as well as the ICESCR. It ratified CEDAW on December 15, 1995, the ICESCR on January 12, 2015 and the ICCPR on December 10, 1998. For the ratification status of these and other international treaties in South Africa, see United Nations (2023) UN Treaty Body Database at https://tbinternet.ohchr.org/_layouts/15/TreatyBodyExternal/Treaty.aspx?CountryID=162&Lang=EN (accessed 22/08/2023).

²⁶² Constitution of the Republic of South Africa, 1996, Article 27.

²⁶³ See Articles 10, 32 and 34 of the Constitution of the Republic of South Africa, 1996 respectively.

²⁶⁴ National Health Act, 2003.

²⁶⁵ *Ibid* at Section 2(c)(iii).

²⁶⁶ Consumer Protection Act, No. 68 of 2008.

and the quality of, information necessary to enable consumers make informed choices and to protect consumers from hazards to their well-being and safety.

Similar to the Kenyan situation, the regulation of sex lubricants is not explicitly provided for in the South African Constitution and in the numerous statutes mentioned above. A glimpse of the regulation of these products for safety in South Africa and Africa in general is found in studies done by scholars particularly among MSMs as discussed in Chapter 2 of this study due to targeted MSM HIV prevention activities.²⁶⁷ Nevertheless, findings of numerous studies have actually indicated that the use of lubricants by heterosexual individuals and MSM during sex in South Africa is neither widespread nor common²⁶⁸ due to a variety of factors.

Some of these circumstances include the fact that the price of lubricants is beyond the amount that individuals can comfortably afford²⁶⁹ while some are unaware of the availability of such products.²⁷⁰ In one paper, it was noted that in the rare instance that lubricants were used during sexual intercourse, non-commercial lubricants most of which are neither condom compatible nor intended for internal use would be used.²⁷¹

Examples of these non-commercial lubricants being used included body lotions, food items such as yoghurt and chocolate spread²⁷² and the widely available and relatively inexpensive petroleum jelly-based products such as Vaseline.²⁷³ As earlier discussed in previous chapters²⁷⁴

²⁶⁷ Zoe Duby, Mirian Hartmann et.al. (2016) “Condoms, lubricants and rectal cleansing: practices associated with heterosexual penile-anal intercourse amongst participants in an HIV prevention trial in South Africa, Uganda and Zimbabwe” *AIDS Behaviour* 754-762 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4698090/> (accessed 07/08/2023).

²⁶⁸ *Ibid.* See also Mathew Lee, Theo Sandfort et.al. (2017) “Breakage is the norm: use of condoms and lubrication in anal sex among Black South African men who have sex with men” 19 *Culture, Health & Sexuality* 501-514 at <https://www.tandfonline.com/doi/epdf/10.1080/13691058.2016.1239134?needAccess=true&role=button> (accessed 07/08/2023).

²⁶⁹ Kabelo Maleke, Nosipho Makhakhe et.al. (2017) “HIV risk and prevention among Men who have Sex with Men in rural South Africa” *African Journal of AIDS Research* 31-38 at <https://doi.org/10.2989/16085906.2017.1292925> (accessed 10/08/2023).

²⁷⁰ *Ibid.*

²⁷¹ Mathew Lee, Theo Sandfort et.al. (2017) “Breakage is the norm: use of condoms and lubrication in anal sex among Black South African men who have sex with men” 19 *Culture, Health & Sexuality* 501-514 at <https://www.tandfonline.com/doi/epdf/10.1080/13691058.2016.1239134?needAccess=true&role=button> (accessed 07/08/2023).

²⁷² *Ibid*

²⁷³ Cf Zoe Duby, Mirian Hartmann et.al. (2016) “Condoms, lubricants and rectal cleansing: practices associated with heterosexual penile-anal intercourse amongst participants in an HIV prevention trial in South Africa, Uganda and Zimbabwe” at 10.

²⁷⁴ Cf Chapters 2 and 3 of this LLM Research Project Paper.

of this study, some of these products particularly petroleum jelly-based products are known to degrade latex and cause condom breakage when used together with condoms, risking to expose such users with unwanted pregnancies, STIs and even HIV/AIDS.

Focus should be directed towards sex lubricants, their use, safety, effectiveness and quality to ensure that South African consumers consume products that are of high quality and standard.

4.3 Regulation of Sex Lubricants for Safety in Nigeria

Similar to the Kenyan²⁷⁵ and South African²⁷⁶ legal environment, sexual and reproductive health rights in Nigeria are safeguarded through a number of international legal instruments that Nigeria is a party to such as the CEDAW, ICESCR and the ICCPR.²⁷⁷

In Nigeria, the right to health, and more specifically, the right to sexual and reproductive health though not explicitly provided as a fundamental human right in the 1999 Constitution is inferred from the provisions of its Chapter II.²⁷⁸ The Chapter outlines the fundamental objectives and directive principles of State policy towards socio-economic rights. Section 17(3)(d) stipulates that the State shall direct its policy towards ensuring that there are adequate medical and health facilities for all persons.

The wording of this Chapter has been deemed problematic as it is seen to enumerate but not guarantee socio-economic rights in Nigeria.²⁷⁹ Scholars have argued that the rights have been outlined as mere directive principles rather than enforceable rights and without clear provisions on enforcement mechanisms.²⁸⁰ As a result, the provisions of the Chapter have been excluded from adjudication by the courts²⁸¹ rendering aggrieved parties with no right of action in

²⁷⁵ Cf Chapter 2 of this LLM Research Project Paper

²⁷⁶ See section 4.2 above.

²⁷⁷ Nigeria ratified CEDAW on June 13, 1985 and acceded to both the ICESCR and the ICCPR on July 29, 1993. See United Nations (2023) “UN Treaty Body Database” at https://tbinternet.ohchr.org/_layouts/15/TreatyBodyExternal/Treaty.aspx?CountryID=162&Lang=EN (accessed 22/08/2023).

²⁷⁸ The Constitution of the Republic of Nigeria 1999, Chapter II.

²⁷⁹ Obiajulu Nnamuchi (2008) “Kleptocracy and its many faces: The Challenges of Justiciability of the Right to Health Care in Nigeria” 52 *Journal of African Law* 1-42 at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1117230 (accessed 25/08/2023).

²⁸⁰ *Ibid.*

²⁸¹ Oluwakemi Amudat Ayanleye (2014) “Women and Reproductive Health Rights in Nigeria” *OIDA International Journal of Sustainable Development* 127-140 at <https://ssrn.com/abstract=2381324> (accessed 25/08/2023).

instances where the Government is in breach of these provisions. Notably, courts in Nigeria in various cases have held consistently that this section of the Constitution is not justiciable.²⁸²

Notably, the Bill of Rights in the Nigerian Constitution are not as elaborate as those in the Kenyan and South African Constitutions. Case in point consumer protection rights are not enshrined in the Nigerian Constitution. They are however safeguarded under the Federal Competition and Consumer Protection Act, an Act that establishes the Federal Competition and Consumer Protection Commission and the Competition and Consumer Protection Tribunal in Nigeria.²⁸³ The Act requires product labeling and trade descriptions to be displayed to goods²⁸⁴ and further protects consumers by affording them various rights. Some of these rights include the right to choose or examine goods, to return unsafe or defective goods at a refund and to receive safe and good quality goods.²⁸⁵ As the Act applies to all citizens, it is deduced that this Act applies to consumers of sex lubricants in Nigeria.

The Nigerian National Health Act, 2014 doesn't explicitly provide for sexual and reproductive health rights. In its preamble, the Act is described as an Act to provide a framework for the regulation, development and management of a national health system and set standards for rendering health services in the federation; and for related matters.

A number of policies however have been instrumental in safeguarding aspects of sexual and reproductive health in Nigeria such as the National Health Policy and Strategy to Achieve Health for All Nigerians, 1988 which was the first comprehensive national health policy.²⁸⁶ Since then, there have been a number of policies such as the National Strategic Health Development Plan (2010-2015), the National Health Sector Reform Programme (2004-2007), the Revised National Health Policy, 2004 and the current National Health Policy, 2016.

²⁸² *Ehimare v. Governor of Lagos State* [1981] 2, NCLR, 166 and *Adewole v. Jakande* [1981] 1NCLR, 262 as cited in Oluwakemi Amudat Ayanleye (2014) "Women and Reproductive Health Rights in Nigeria" *ibid*.

²⁸³ Federal Competition and Consumer Protection Act, 2018.

²⁸⁴ *Ibid* at section 116.

²⁸⁵ *Ibid* at sections 121, 122 and 131 respectively.

²⁸⁶ Federal Ministry of Health (1988) *National Health Policy and Strategy to Achieve Health for all Nigerians* at <https://thedocs.worldbank.org/en/doc/929691562140346971-0240021988/render/WorldBankGroupArchivesFolderD204877.pdf> (accessed 25/08/2023).

The objectives of the National Health Policy, 2016 is among others to ensure the awareness of, and access to comprehensive reproductive health services.²⁸⁷ Despite the fact this policy document doesn't specifically govern the regulation of sex lubricants, it is a step in the right direction as it provides for sexual and reproductive health services to its citizenry.

Similar to the South African legal environment, an understanding of the regulation of sex lubricants for safety in Nigeria is derived from studies conducted on the behavior of MSM and their use of condoms and sex lubricants. This study relies on two studies conducted in Lagos and Abuja, Nigeria.

In one of the studies conducted in Lagos, it was noted that the use of lubricants by MSM is quite low despite the fact that 62.9% of the study participants reported access to both condoms and lubricants.²⁸⁸ Some of those that did use lubricants during sex were reported to have used non-water based lubricants with petroleum jelly being the most common alternative lubricant.²⁸⁹ The safety concerns of using petroleum jelly as a lubricant are plenty and have been discussed in previous chapters of this study.

In yet another study conducted in Lagos in 2013, the results slightly differed from the study discussed above and reflected that most of the respondents actually used lubricants during sex.²⁹⁰ In as much as this is commendable, it is alarming that some respondents used body creams, saliva and even Vaseline as lubricants. The safety concerns of using such products cannot be stressed enough and has been covered adequately in previous chapters of this study. Finally, the study explained that the few who did not use lubricants during sex, refrained due to a variety of factors – some believed they did not need it and some did not know that lubricants were useful.²⁹¹

²⁸⁷ Federal Ministry of Health (2016) *National Health Policy 2016* at <https://www.health.gov.ng/doc/National-Health-Policy-2016-21032019.pdf> (accessed 25/08/2023).

²⁸⁸ Trevor Crowell, Stephan Baral et.al. (2019) "Time to Change the Paradigm: Limited Condom and Lubricant Use among Nigerian Men who have Sex with Men and Transgender Women despite Availability and Counseling" at *Annals of Epidemiology* 11-19 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6732794/> (accessed 30/08/2023).

²⁸⁹ *Ibid.*

²⁹⁰ Oluyemisi Ayoola, Adekemi Sekoni and Kofoworola Odeyemi (2013) "Transactional sex, condom and lubricant use among Men who have Sex with Men in Lagos State, Nigeria" *African Journal of Reproductive Health* 90-98 at <https://www.ajrh.info/index.php/ajrh/article/view/304> (accessed 30/08/2023).

²⁹¹ *Ibid.*

4.4 Regulation of Sex Lubricants by Regulatory Agencies in other Jurisdictions

The Food and Drug Administration (FDA) is a federal agency of the department of health and human services in the United States of America. The agency is responsible for protecting the public health by ensuring the safety, efficacy and security of among other things, medical devices and by ensuring the safety of the nation's food supply, cosmetics and products that emit radiation.²⁹²

Previously sex lubricants had been minimally regulated by the FDA. This was because these products caused minimal health risks. Furthermore, most of these products claimed to moisturize or cleanse and as such were classified as cosmetics.²⁹³ Under the 1976 FDA regulations, lubricants were considered medical devices if they were intended for medical purposes that is in being used to lubricate a body orifice to facilitate the entry of a diagnostic or therapeutic device.²⁹⁴ Therefore sex lubricants would either be considered cosmetics or medical devices depending on their marketing or what the products claimed they did.

However this stance changed over the years when the use of sexual lubricants containing nonoxynol-9 (N-9), an organic compound used as a vaginal spermicide negatively affected consumers who used it. Most water based lubricants contained this compound in their ingredients as it is relatively cheap.²⁹⁵ It was however shown to directly enhance the acquisition and increase the transmission of HIV in some of its users.²⁹⁶

This prompted more research to be conducted on sex lubricants that were in the market at the time. Studies found that some sex lubricants in the market presented pH and/or component concentrations (osmolality) values outside the ranges recommended by the World Health

²⁹² Food and Drug Administration (2020) "What we do" at <https://www.fda.gov/about-fda/what-we-do> (accessed 9/10/2020).

²⁹³ Cf Scott Geibel (2013) "Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa" *Journal of the International AIDS Society* 2-3.

²⁹⁴ FDA regulation 21 CFR 880.6375

²⁹⁵ Cf Michael Stafford, Helen Ward, Adrienne Falanagan et.al (1998) "Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*.

²⁹⁶ *ibid.*

Organization (WHO).²⁹⁷ Studies showed that these differences could adversely affect the sexual and reproductive health of users of these devices.

As a result of these emerging concerns, the FDA became more rigorous in regulating sex lubricants. In 2003, the FDA announced a safety and efficacy review.²⁹⁸ In its review, the Agency considered claims related to relieve discomfort and those that sought to comfort and ease sexual activity to be drug claims as they relate to the mitigation or treatment of disease as per section 201(g)(1)(B) of Food, Drug and Cosmetic Act. Furthermore, products that affected the structure or function of the body would also be considered as drugs in conformity with section 201(g)(1)(C) of the Act.

Additionally, the review indicated that products that were marketed as vaginal moisturizers would also be considered as drugs. This is because they did not relate to the cleansing, beautifying or promoting of attractiveness or altering appearance. Instead, these products were seen to affect the structure or function of the body and in some cases may mitigate diseases.²⁹⁹

Classifying sex lubricants as medical devices therefore means that these products require the Agency's approval commonly referred to as a premarket notification (PMN) or a 510(k) clearance before being released to the market. Section 510(k) of the of the United States' Food, Drug and Cosmetic Act provides that a premarket notification (PMN) is required before medical device manufactures register and notify the agency of their intention to market a medical device at least 90 days in advance.

Medical devices in the US need not disclose the ingredients used to manufacture the products on their packaging. This presents a challenge to consumers of these products as they are unable to know and understand what type of ingredients are introduced to their body.

²⁹⁷ Cunha, Machado, de-Oliveira (2014) "Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective, *op.cit.*, at 155.

²⁹⁸ Federal Register (2003) "Over the counter drug products; safety and efficacy review," at at <https://www.federalregister.gov/documents/2003/12/31/03-32102/over-the-counter-drug-products-safety-and-efficacy-review> accessed (22/09/2020).

²⁹⁹ *ibid.*

Further afield in Europe, the European Medicines Agency (EMA), a decentralized agency of the European Union (EU) is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.³⁰⁰

The EMA requires medical devices to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure that they are safe and perform as intended.³⁰¹ It classifies sex lubricants as class IIa medical devices. As a result, these devices are excluded from extensive pre-clinical and clinical testing required for other drugs.³⁰²

Another organization that is crucial for the regulation of sex lubricants for safety is the International Organization for Standardization (ISO). The ISO is an independent, non-governmental international organization whose mandate is to bring experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.³⁰³

The Organization is made up of 165 national standard bodies, to which Kenya is one of the members. Condoms and lubricants are usually tested according to standardized guidelines by the Organization such as ISO 19671:2018 ‘Additional lubricants for male natural rubber latex condoms’.

Apart from these two regulatory agencies, there is scarcity of literature on the regulation of sex lubricants.

4.5 Case Law concerning Regulation of Sex Lubricants for Safety

A class action suit was instituted in 2015 in a California federal court against lubricant maker Love Honey, Inc., the store where the lubricant was sold and against the author of the novel *Fifty Shades of Grey*.³⁰⁴

³⁰⁰ European Medicines Agency (2020) “Who we are” at <https://www.ema.europa.eu/en/about-us/who-we-are> (accessed 27/09/2020).

³⁰¹ *ibid*

³⁰² Nicole Weendee (2014) “A question for women’s health: Chemicals in feminine hygiene products and personal lubricants” *Environmental Health Perspectives* A70-A75 at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948026/> (accessed 26/09/2020).

³⁰³ International Organization for Standardization (2020) “About Us,” at <https://www.iso.org/about-us.html> (accessed on 21/09/2020).

³⁰⁴ *Tania Warchol (f/k/a Tania Racha) et al. v. Love Honey Inc* Case No. 3:15-cv-00238 [2015] (US).

The plaintiff in the matter purchased the lubricant named Fifty Shades of Grey Come Alive Pleasure Gel for Her³⁰⁵ based on the novel and movie of the same name. The packaging on the lubricant indicated that use of the lubricant would lead to enhanced orgasms and stimulation.

The plaintiff claimed that upon using the lubricant, she did not experience what the packaging contended it would enhance. She further contended that the lubricant lacked the ingredients that will allow users to experience stimulation, pleasure, and orgasm.

Additionally, the plaintiff contended that the lubricant did not receive the required approvals by the Food and Drug Administration (FDA) and was neither listed as a class I medical device nor a class II medical device by the FDA. Finally, the plaintiff contended that as a result of the alleged lack of FDA approval, the lubricant was being illegally marketed and sold as being latex compatible.

The plaintiff therefore sought relief from the court for damages and sought the manufacturer to modify their advertising on the lubricant. It is unclear what the outcome of the suit was but this is an interesting development in this area of the law that could be emulated by dissatisfied users of sex lubricants in Kenya and beyond.

4.6 Lessons Kenya can learn on the Regulation of Sex Lubricants for Safety

From the foregoing discussion, this study recognizes that there is a dearth of regulatory agencies governing sex lubricants in Kenya, South Africa and Nigeria. Most of the regulatory controls governing sex lubricants are from the US Food and Drug Administration (FDA) which lists sex lubricants as class II medical devices.

This study suggests that Kenya as well as other African countries should be guided and perhaps adopt the FDA's classification of sex lubricants. This classification should be added as a provision in Kenya's Reproductive Healthcare Bill before it is assented and enacted into law. Furthermore, the subsidiary legislation of the Bill should contain extensive regulations that cover the regulation of sex lubricants in Kenya. This should also be done in statutes governing sexual and reproductive health in South Africa and Nigeria.

³⁰⁵ A quick browse on the internet indicates that the gel is still being sold with some websites indicating that the gel "enhances orgasms and stimulation within a few minutes of application".

These regulations should be in conformity with the ISO standards on sex lubricants. This study also suggests that regulatory agencies in these countries such as the Kenya Bureau of Standards (KEBS) should also lay out specific standards that are to regulate sex lubricants and other medical devices expressly.

4.7 Conclusion on the Comparative Study on the Regulation of Sex Lubricants in other Jurisdictions.

This chapter has made a comparative study on the regulation of sex lubricants in South Africa, Nigeria and of the US's FDA, the EMA in Europe and the ISO. The chapter discussed how these agencies regulate sex lubricants and their classification.

From this study, it is evident that there is a scarcity of regulations governing sex lubricants for safety as study in this area is limited. The FDA is the only regulatory agency that has comprehensive guidelines on the regulation of sex lubricants for safety. However, the guidelines are also limited as there are a number of safety concerns arising from the use of sex lubricants that are not covered by the FDA regulations.

The chapter has also discussed lessons that Kenya can learn and emulate from the comparative analysis of the regulation of sex lubricants for safety. This study argues that the relevant statutes governing reproductive health and standards for medical devices namely the Reproductive Health Act and the Standards Act should expressly have provisions for the regulation of sex lubricants in Kenya.

The next chapter is the final chapter of this study. It will give a summary of the findings, conclusion and recommendation on the regulation of sex lubricants for safety in Kenya.

CHAPTER 5
FINDINGS, CONCLUSIONS AND RECOMMENDATIONS
ON THE REGULATION OF SEX LUBRICANTS FOR SAFETY IN KENYA

5.1 Introduction on the Findings, Conclusion and Recommendations on the Regulation of Sex Lubricants for Safety in Kenya

The overarching research objective, research question and argument of this thesis is that the regulation of sex lubricants in Kenya is integral in ensuring that the reproductive health and safety of consumers of these devices are safeguarded.³⁰⁶

This study's chapters 1 to 4 established the need for this study and discussed in detail the research objectives, research questions and research hypothesis on the regulation of sex lubricants for safety in Kenya and beyond. The previous chapter, Chapter 4 addressed the third research objective of this study by making a comparative analysis of the varied regulations of sex lubricants in South Africa, Nigeria and in other regulatory agencies such as the FDA in the US and the EMA in Europe.³⁰⁷ It identified lessons that Kenya can learn on the regulation of these devices. It is on the backbone of the findings of chapters 1 to 4 of this study that this conclusive chapter is premised.

This final chapter, Chapter 5 seeks to revisit and discuss the findings of each of the previous chapters and give recommendations on the regulation of sex lubricants for safety in Kenya. Lastly, this chapter will make a conclusion on this exploratory study.³⁰⁸

5.2 Research Objectives on the Regulation of Sex Lubricants for Safety in Kenya

This study has been guided by a specific research objective and three (3) general objectives outlined as follows:

The specific research objective of this thesis is to critically analyze the regulatory controls relating to sex lubricants that ensure their safety in Kenya.³⁰⁹

³⁰⁶ See chapter 1.1 of this LLM Research Project Paper.

³⁰⁷ Cf Chapter 4 of this LLM Research Project Paper.

³⁰⁸ Ben Sihanya (2023) *Sihanya Mentoring LLM Thesis and Research Project Paper Guidelines*, Innovative Lawyering and Sihanya Mentoring, Nairobi & Siaya.

³⁰⁹ Cf. Chapter 1 of this LLM Research Project Paper.

Apart from this specific research objective, this thesis also seeks to achieve the following general objectives namely:³¹⁰

First, to discuss the national and international legal frameworks and regulations pertaining to sex lubricants in Kenya. This was discussed in Chapter 2 of this study.

Second, to discuss the limitations arising from the legal frameworks and regulations as well as the safety concerns arising from these limitations in Kenya. This was also discussed in Chapter 3 of this study.

Third, to make recommendations from a comparative study of countries such as South Africa and Nigeria and regulatory agencies such as the FDA in the USA and the EMA in Europe on how to improve the available laws and regulations pertaining to sex lubricants in Kenya. This was discussed in Chapter 4 of this study.

5.3 Research Questions on the Regulation of Sex Lubricants for Safety in Kenya

Alongside the research objectives enumerated above, this study sought to answer the following three (3) research questions:³¹¹

As discussed in Chapter 2 of this study, first, what are the national and international legal frameworks, regulations and guidelines on sex lubricants in Kenya?

Second, as discussed in Chapter 3, what are the limitations arising from the legal frameworks, regulations and guidelines? Additionally, what safety concerns arise from these limitations?

Third, as discussed in Chapter 4, what recommendations can be made from the comparative study of South Africa, Nigeria and regulatory agencies such as the FDA in the USA, and the EMA in Europe to improve and fill in the lacuna in the available laws and regulations on sex lubricants in Kenya with regard to operationalizing Articles 43(1)(a) and 46 of the Constitution 2010?

³¹⁰ Cf Chapter 1 of this LLM Research Project Paper.

³¹¹ *Ibid.*

5.4 Hypotheses and Assumptions on Limitations of Regulating Sex Lubricants for Safety in Kenya

This thesis argues that the legal framework and regulations on sex lubricants in Kenya is limited and largely silent. There is need to amend and harmonize all the relevant laws and regulations in order to specifically define, categorize and provide a regulatory framework of the manufacture and use of sex lubricants in Kenya.

This study makes the following hypotheses and assumptions:

First, the available and relevant statutes and regulations concerning sex lubricants in Kenya do not explicitly mention or categorize sex lubricants and their regulation.³¹² This creates a lacuna in the Kenyan laws in this area of study leaving us to rely on the mode of regulations of these devices from other jurisdictions for guidance.

Second, Kenya needs to adopt a clear legal framework on the regulation of sex lubricants with guidance from the International Organization for Standards (ISO)³¹³, the Food and Drug Administration (FDA)³¹⁴ and the European Medicines Agency (EMA)³¹⁵ to ensure that the safety and sexual and reproductive health of users of these devices are protected.

5.5 Findings on the Study on the Regulation of Sex Lubricants for Safety in Kenya

Chapter 2 of this study interrogated and discussed the legal framework of regulation of sex lubricants in Kenya and internationally. The Chapter discussed the various constitutional and statutory laws that govern sexual and reproductive healthcare in Kenya, as well as the legal framework in South Africa, Nigeria and regulatory agencies such as the FDA in USA and the EMA in Europe.

³¹² Cf Chapter 2 of this LLM Research Project Paper. Over the 15 statutes, bills, regulations and guidelines analyzed, none specifically make a mention of lubricants nor their use, safety and regulation.

³¹³ International Standard Organization (2023) ISO 19671:2018 Additional lubricants for male natural rubber latex condoms – Effect on condom strength at <https://www.iso.org/obp/ui/en/#iso:std:iso:19671:ed-1:v3:en> (accessed 15/06/2021).

³¹⁴ Cf. Food and Drug Administration (2020) “Product classification”) See also Federal Register (2003) “Over the counter drug products; safety and efficacy review.

³¹⁵ Cf European Medicines Agency (2020) “Who we are”.

The findings from that chapter are that jurisdictions that have regulatory mechanisms of sex lubricants in place categorize them as medical devices.³¹⁶ Sex lubricants are integral in the sexual and reproductive healthcare of individuals who use these devices as they are directly used in the genitalia of its users³¹⁷ to moisturize and lubricate and to enhance the ease and comfort of intimate sexual activity by supplementing the body's natural lubrication.³¹⁸ As sex lubricants affect the sexual and reproductive healthcare of individuals who use them, such users are protected under Article 43 of the Constitution of Kenya which guarantees and protects the economic and social rights of its citizenry.³¹⁹

Users of sex lubricants are protected by various Articles of the Constitution. First, consumers of sex lubricants – persons to whom sex lubricants are marketed to in the ordinary course of the supplier's business - are protected under Article 46 of the Constitution as well as the Consumer Protection Act, 2012.³²⁰ Article 46 of the Constitution and the provisions of the Consumer Protection Act are particularly important to consumers of sex lubricants as they guarantee that such users purchase sex lubricants that are of reasonable quality. Additionally, they guarantee that such users receive information necessary for them to gain full benefit from the goods and avail an avenue in which such users can be compensated in instances where they occasion injury resulting from the defects of sex lubricants.³²¹

Second, users of sex lubricants are further protected by Article 35 of the Constitution that affords them the right to access information that is necessary for them to gain full benefit from the use of sex lubricants. The Access to Information Act, 2016 gives effect to this provision of the Constitution. It provides a framework for both public and private entities to proactively disclose information that they hold.³²²

³¹⁶ Sex lubricants are generally categorized as medical devices by the FDA and the EMA.

³¹⁷ Cf. WHO (2012) *Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360*, Advisory note, Switzerland.

³¹⁸ Cf. Food and Drug Administration (2020) "Product classification" at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NUC> (accessed 14/05/2020).

³¹⁹ Specifically, the Article guarantees every individual the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.

³²⁰ Consumer Protection Act, 2012. Cf Chapter 2 of this LLM Research Project Paper.

³²¹ *Ibid* at part II.

³²² Access to Information Act 2016, s3(b).

This thesis argues that this provision extends to relaying all information concerning sex lubricants to the general public. The Act is therefore important as it arms consumers of sex lubricants with the power to seek all the necessary information with regard to the quality, use and components used in the manufacturing of sex lubricants from the state as well as manufacturers of these devices. As a result, consumers of these devices can purchase sex lubricants having adequate information about their quality and effectiveness.

Third, consumers of sex lubricants are afforded various protective measures by the National and County Governments that have the mandate to *inter alia* oversee consumer protection and health services and critically to formulate health policies.³²³ From a reading of all the constitutional provisions, it is evident that the National Government is primarily responsible for the enhancement and promotion of sexual and reproductive health rights in Kenya.

There are also various other protective measures afforded to consumers of sex lubricants through numerous Kenyan statutes and bills discussed in detail in Chapter 2 of this study.³²⁴ These laws include the Health Act, 2017, the Pharmacy and Poisons Act,³²⁵ the Standards Act,³²⁶ and its corresponding Standards Bill, 2019, the Reproductive Healthcare Bill, 2019 and the Kenya Food and Drugs Authority Bill.

All these Constitution and statutory provisions and bills are commendable as they indirectly protect consumers of sex lubricants. They also play a secondary role of limiting governmental power³²⁷ in instances when a freedom is infringed by the Government or any other person, the claimant may have redress.³²⁸ However, none of these statutes nor bills explicitly define what sex lubricants are and as such they barely provide for specific regulation of these products for safety for the benefit of consumers of these products in Kenya.

³²³ See the 4th Schedule of the Constitution of Kenya, 2010.

³²⁴ Cf Chapter 2 of this LLM Research Project Paper.

³²⁵ Chapter 244 of the Laws of Kenya,

³²⁶ Chapter 496 of the Laws of Kenya

³²⁷ Ben Sihanya (2023) *Constitutional Democracy, Regulatory and Administrative Law in Kenya and Africa Vol 1: Presidency, Premier, Legislature, Judiciary, Commissions, Devolution, Bureaucracy and Administrative Justice in Kenya*, Sihanya Mentoring & Prof Ben Sihanya Advocates, Nairobi & Siaya

³²⁸ See Articles 19-25 and Articles 47-51 of the Constitution of Kenya, 2010. Article 23 particularly arms users of sex lubricants with the option of going to the High Court to enforce their rights in instances where their sexual and reproductive rights are violated.

There are a number of institutions that are integral in the regulation of sex lubricants. These have been extensively discussed in Chapter 2 of this study and shall be briefly highlighted here.

³²⁹ First, being the Kenya Bureau of Standards (KEBS), established by section 3 of the Standards Act whose objective is to promote standardization in industry and commerce, to prepare, frame, modify or amend specifications and codes of practice and to assist in the production of quality goods.³³⁰

Second, the Consumer Federation of Kenya (COFEK) protects the consumer rights of individuals by defending, promoting, developing and pursuing consumer rights in line with Article 46 of the Constitution of Kenya as well as the Consumer Protection Act, 2012 and the Competition Act, 2010. As users and buyers of sex lubricants are considered as consumers of goods, they are also protected by this Federation.

Third, the state corporation, Kenya Medical Supplies Authority (KEMSA), established under section 3 of the Kenya Medical Supplies Authority Act, 2013 has the function of procuring and distributing medical supplies for prescribed health programs.³³¹ This specific role of KEMSA intersects with the role of KEBS as goods and in this instance sex lubricants procured by KEMSA have to be of good quality and of an agreeable standard as per KEBS.

There are various regional and international legislative frameworks guiding sex lubricants.³³² African legislative instruments recognizing reproductive health rights include the African Charter on Human and Peoples' Rights ACHPR (Banjul Charter) and the Maputo Protocol to the Banjul Charter.

Internationally, various legal instruments safeguard sexual and reproductive rights of individuals. These include instruments on discrimination against women - The Convention on the Elimination of all Discrimination Against Women (CEDAW), instruments on general human rights - the Universal Declaration of Human Rights (UDHR), instruments on socio-economic rights - the International Covenant on Economic, Social and Cultural Rights

³²⁹ Cf Chapter 2 of this LLM Research Project Paper.

³³⁰ The Standards Act, Cap 496 Laws of Kenya.

³³¹ Kenya Medical Supplies Authority (2022) "Legal Mandate" at <https://www.kemsa.co.ke/legal-mandate/> (accessed 11/8/2022).

³³² Cf Chapter 2 of this LLM Research Project Paper

(ICESCR), instruments pertaining civil rights - the International Covenant on Civil and Political Rights (ICCPR) and even instruments safeguarding the rights of people living with disability - the Convention on the Rights of Persons with Disabilities (CRPD) among numerous other legislative frameworks all recognize and uphold the sexual and reproductive health rights of individuals.

Chapter 3 of this study on the other hand, discussed the safety concerns arising from the regulation or lack thereof of sex lubricants in Kenya.³³³ Some studies have indicated that when used, some water-based sex lubricants may induce changes to the vaginal environment of its users that may have devastating effects specifically on their reproductive health.³³⁴

Other safety concerns arising and discussed in Section 3.2.2 include problems with the classification of sex lubricants. Generally, sex lubricants are classified as medical devices by the Food and Drug Administration (FDA)³³⁵ and the European Medicines Agency (EMA).³³⁶ As discussed in Chapter 3 of this study, classifying sex lubricants as medical devices excludes them from extensive pre-clinical and clinical testing done on all other drugs in the USA and in Europe.³³⁷

Additionally, some sex lubricants in the market claim to moisturize or cleanse when used topically and as such are often considered as cosmetics.³³⁸ This particular classification of these devices as cosmetics is alarming as devices categorized as cosmetics are exempted from further and intensive regulatory mechanisms by the FDA and the EMA. This stance has however been reversed by the FDA which categorizes sex lubricants that claim to decrease pain, enhance sexual pleasure or contain spermicide as drugs.³³⁹

³³³ Cf Chapter 3 of this LLM Research Project Paper

³³⁴ Cf Cunha, Machado, Palmeira-de-Oliveira et. al (2014) "Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective".

³³⁵ FDA (2020) "Product classification" *op.cit.* at 5.

³³⁶ Cf UNFPA (2016) "Global Consultation on Personal Lubricants."

³³⁷ Cf Weendee (2014) "A question for women's health: Chemicals in feminine hygiene products and personal lubricants".

³³⁸ Cf Geibel (2013) "Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa".

³³⁹ Cf FDA (2003) "Over-the-counter drug products; safety and efficacy review".

Yet another safety concern arising from the use of sex lubricants as discussed in section 3.2.3 of this study stems from the fact that some studies³⁴⁰ have shown that most sex lubricants contain harmful ingredients that may negatively affect the sexual and reproductive health of its users. Alarming, in most severe cases, use of these sex lubricants can increase the risk of users contracting the HIV infection in women.³⁴¹

The Chapter 3 also found out that some studies have indicated that most sex lubricants in the market present hydrogen potential (pH) and/or component concentrations (osmolality) values outside the ranges recommended by the WHO.³⁴² These stark differences in pH on these sex lubricants have been shown to adversely affect the vagina of its users and therefore directly impact their sexual and reproductive health.

Closer home, multiple studies conducted in the country indicate that Men who have Sex with Men (MSM) largely use sex lubricants when engaging in sexual activity.³⁴³ These studies however revealed that most of these MSM indicated that the available sex lubricants in the Kenyan market are largely unaffordable.³⁴⁴ This situation was seconded by the Ministry of Health and the National AIDS Control Council in its National AIDS strategic plan.³⁴⁵ As a result, MSM and users of sex lubricants generally are left to resort to using saliva, margarine, herbs, coconut oil, Vaseline and cooking oil³⁴⁶ to assist in lubrication during sexual activity. The same situation is also experienced in South Africa and Nigeria as discussed in Chapter 4

³⁴⁰ Cf Stafford, Ward, Falanagan et.al (1998) “Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects,” *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*.

³⁴¹ *ibid* also Cf WHO/CÓNRAD (2003) “*Technical Consultation on Nonoxynol- 9*,” at https://apps.who.int/iris/bitstream/handle/10665/68510/WHO_RHR_03.08.pdf;jsessionid=F8AE1431BBD208ABB6B746D2E5C8BB70?sequence=1.

³⁴² Cf Cunha, Machado, de-Oliveira 2014) “Characterization of Commercially Available Vaginal Lubricants: A Safety Perspective.

³⁴³ Cf Chapter 3 of this LLM Research Project Paper.

³⁴⁴ Cf Kenya National Commission on Human Rights (2012) *Realising Sexual and Reproductive Health Rights in Kenya: A myth or Reality?* Nairobi.

³⁴⁵ Cf Ministry of Health (2014) *Policy analysis and advocacy decision model for services for key populations in Kenya* at https://www.healthpolicyproject.com/pubs/744_KenyaMSMDecisionModelReportFORMATTEDfinal.pdf, Nairobi.

³⁴⁶ Cf Amy Fallon (2016) “Tanzania has banned lubricants over the belief that it "promotes homosexuality” at <https://www.sbs.com.au/topics/pride/agenda/article/2016/10/07/tanzania-has-banned-lubricants-over-belief-it-promotes-homosexuality>.

of this study.³⁴⁷ It goes without saying that the use of such substances during sexual activity can be extremely harmful to the sexual and reproductive health of users.

Chapter 3 of this study also discussed that the Institute of Primate Research (IPR) based in the Kenya National Innovation Agency, an ISO certified biomedical research institution in Kenya manufactures and has introduced a water-based and water soluble sex lubricant known as Smugel to the Kenyan market. This comes as a reprieve to the users of sex lubricants in Kenya as the sex lubricant is said to not induce any adverse effects that may facilitate the transmission of STIs and pathogens such as HIV when used by users.³⁴⁸

It is arguable that with the manufacturing of a sex lubricant locally, more users can be able to use this sex lubricant as it is likely to be cheaper as compared to other foreign manufactured sex lubricants. A visit in the Kenyan local pharmacies³⁴⁹ indicated that a 50 gram tube of Smugel Lubrication Gel costs an average of Kenya Shillings 310 while an 82 gram tube of KY Jelly costs an average of Kenya Shillings 1,200. In comparison, Smugel Lubrication Gel is way cheaper and from the study enumerated earlier³⁵⁰, could be way safer to use by users of sex lubricants.

Finally, chapter 4 of this study made a comparative analysis of the regulation of sex lubricants for safety in other jurisdictions namely the United States of America through the FDA, Europe through the EMA and internationally generally through the International Organization for Standardization (ISO) as compared to Kenya.

Chapter 4 of this study discussed that the FDA currently employs stringent regulatory controls and categorizes sex lubricants as medical devices as opposed to cosmetics. This is after the FDA conducted a safety and efficacy review following concerns that some sex lubricants contained nonoxynol-9 (N-9), an organic compound that negatively affected its consumers.³⁵¹

³⁴⁷ Cf Chapter 4 of this LLM Research Project Paper.

³⁴⁸ Cf Jael Obiero, Robert Kunyera, Kenneth Waititu and others (2019) "A comparative study of Smugel and KY Jelly vaginal lubricating gels," *Journal of Reproduction & Contraception*.

³⁴⁹ This visit was done in November 2022 at three different pharmacies located in Nairobi.

³⁵⁰ *Ibid*.

³⁵¹ Cf Michael Stafford, Helen Ward, Adrienne Falanagan et.al (1998) "Safety study of Nonoxynol-9 as a vaginal microbicide: Evidence of adverse effects," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*.

Alarming, most water based lubricants contain this compound in their ingredient list owing to the fact that it is relatively cheap and is effective as a vaginal spermicide.³⁵²

The EMA on the other hand classifies sex lubricants as class IIa medical devices. Medical devices under the EMA are required to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure that they are safe and perform as intended and as such sex lubricants undergo the same assessment.³⁵³ Apart from this assessment, there is scarcity of information of other regulatory controls employed by the EMA to regulate sex lubricants.

Chapter 4 discussed a class action suit instituted in 2015 against a lubricant maker Love Honey, Inc., and the author of the novel Fifty Shades of Grey for misleading a consumer of the product over the product's efficacy.³⁵⁴ It is unclear if the suit was concluded but it is interesting to note that consumers have the right to institute suits over the efficacy of sex lubricants.

Finally, chapter 4 of this study discussed the lessons that can learn on the regulation of sex lubricants for safety and made a conclusion on the comparative study of the regulation of sex lubricants in Kenya, South Africa and regulatory agencies such as the FDA in the US and the EMA in Europe.

5.6 Conclusion on the Study of the Regulation of Sex Lubricants for Safety in Kenya

This exploratory study focuses on the right of all individuals to attain the highest attainable standard of sexual and reproductive healthcare particularly when using sex lubricants. This exploratory study focuses on the right of all individuals to attain the highest attainable standard of sexual and reproductive healthcare particularly when using sex lubricants. From the analysis of the current legal frameworks in Kenya, this study concludes that there are inadequate laws and regulations that govern the regulation of sex lubricants. Majority of the laws discussed acknowledge that sexual and reproductive health is a human right. They also recognize the right to family planning services, abortion services and maternal health services but do not explicitly cover sex lubricants.

³⁵² *ibid.*

³⁵³ Cf European Medicines Agency (2020) "Who we are" at <https://www.ema.europa.eu/en/about-us/who-we-are> (accessed 27/09/2020).

³⁵⁴ *Tania Warchol (f/k/a Tania Racha) et al. v. Love Honey Inc* Case No. 3:15-cv-00238 [2015] (US).

Second, from the analysis of the safety concerns arising out of the limitations of the legal framework in Kenya, this study concludes that there are several safety concerns that arise when using sex lubricants. Some of these include the various classifications of sex lubricants as either medical devices or cosmetics, the components that constitute sex lubricants and the variation of pH levels of the sex lubricants from that of the genitals.

Third, from the comparative analysis of the regulation of sex lubricants in various jurisdictions, this study concludes that there is a scarcity of regulations governing sex lubricants for safety as study in this area is limited. The FDA is the only regulatory agency that has comprehensive guidelines on the regulation of sex lubricants for safety. However, the guidelines are also limited as there are a number of safety concerns arising from the use of sex lubricants that are not covered by the FDA regulations.

5.7 Recommendations on Regulation of Sex Lubricants for Safety in Kenya

This study on the regulation of sex lubricants for safety in Kenya was inspired by the limited regulatory controls over these devices in the country and its corresponding effect of attaining and operationalizing the socio-economic and sexual and reproductive health rights of users of these devices.³⁵⁵

From the findings in Chapters 2 to 4 of this study, this thesis recommends that a harmonized national regulatory framework for the regulation of sex lubricants should be put in place. By so doing, the sexual and reproductive health of consumers of sex lubricants will be protected as per Article 43(1)(a) of the Constitution as they will be able to access sex lubricants that are of the highest quality, that are safe and effective. This study recommends that sex lubricants should be explicitly defined and more importantly, categorized as medical devices or health products in all the relevant statutes that are required to regulate them.

Categorizing sex lubricants as medical devices or health products is important in various ways. First, there are statutes that are in place that regulate health products/medical devices. As discussed in Chapter 2 of this study, the Pharmacy and Poisons Act for example employs an extending definition of what health products are by including medical devices as health

³⁵⁵ This is in line with Articles 43 and 46 of the Constitution of Kenya, 2010. Cf Chapter 1 of this LLM Research Project Paper.

products.³⁵⁶ Furthermore, section 2 of the Act defines what medical devices are in detail. By extending this definition to sex lubricants, this study argues that consumers of such products will greatly benefit as these devices will undergo rigorous testing as all other products defined as medical devices in the Act.

The Health Act, 2017 is yet another statute that has in place a regulatory framework for the regulation of among other things, health products and health technologies. The Act further establishes a single regulatory body tasked with the mandate to regulate health products and health technologies. By extending the definition of health products in this Act to include sex lubricants, there is a guarantee that such devices will undergo rigorous testing before they are introduced to the market and marketed to the consumers as safe to use.

This study also recommends that the Government should promote research, innovation and production done by local agencies, institutions and private companies involved in the manufacturing of sex lubricants such as the Institute of Primate Research based in Kenya that manufactures Smugel, a water based and water soluble lubricant.³⁵⁷ This can be done by providing funding specifically targeted towards the research of sex lubricants through the National Research Fund (NRF) established under section 32 of the Science, Technology and Innovation Act, 2013.

Stakeholders in this field should also be encouraged to work alongside the National Commission for Science, Technology & Innovation (NACOSTI) established under section 3 of the Science, Technology and Innovation Act. One of the objectives of NACOSTI is to regulate and assure quality in the science, technology and innovation sector in Kenya.³⁵⁸

The Kenya National Innovation Agency (KENIA) is also established under the Science, Technology and Innovation Act.³⁵⁹ It is yet another collaborative avenue that can be used by stakeholders in the manufacturing of sex lubricants in Kenya as the Agency has among other

³⁵⁶ See section 2 of the Act, Chapter 244 of the Laws of Kenya.

³⁵⁷ Cf Chapter 3 of this LLM Research Project Paper.

³⁵⁸ Science, Technology and Innovation Act 2013, s 4.

³⁵⁹ See section 28 of the Act.

functions, the task to establish and regularly update a database on innovation in collaboration with other relevant institutions.³⁶⁰

Institutes such as the Kenya Medical Research Institute (KEMRI) established through the Science and Technology Act,³⁶¹ tasked with carrying out research in human health in Kenya³⁶² should be empowered to conduct extensive research on the use, efficacy and safety of sex lubricants currently found in the Kenyan market.

Lastly, this study recommends that the Kenyan Government should through the Kenya Bureau of Standards (KEBS) ensure that the sex lubricants imported to our market and those that are manufactured locally are of the highest quality, free from compounds that could be detrimental to consumers who use them.³⁶³ Additionally, KEBS should ensure and guarantee the consumers of sex lubricants that such devices are safe to use and are effective.³⁶⁴

All these recommendations and strategies put forward by this study would ensure that there is an availability of relatively cheaper and more affordable sex lubricants in the market that are of the highest quality, that are safe and effective to use by their consumers.

In conclusion, sexual and reproductive health rights are critical rights that affect the physical, mental and social well-being of individuals.³⁶⁵ Affording people safe, reliable, effective and high-quality lubricants should be high in the Kenyan Government's agenda as it safeguards not only their sexual and reproductive health rights but also their right to human dignity.

³⁶⁰ Science, Technology and Innovation Act 2013, s 29.

³⁶¹ Cap 250 Laws of Kenya (now repealed)

³⁶² Kenya Medical Research Institute (2022) 'Who We Are' at <https://www.kemri.go.ke/background/> (accessed 14 November, 2022).

³⁶³ Cf Chapter 3 of this LLM Research Project Paper.

³⁶⁴ Cf Chapter 2 of this LLM Research Project Paper.

³⁶⁵ Cf United Nations Population Fund (2022) "Sexual and Reproductive Health."

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