

**THE REGULATION OF ONLINE PHARMACIES DISPENSING PRESCRIPTION-  
ONLY MEDICINES IN KENYA: A CONSUMER PROTECTION PERSPECTIVE**

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## DECLARATION

I, MARGARET ATSIENO ZALO, hereby declare that this research is my original work and that, to the best of my knowledge, it has not previously been submitted to any other institution for any other qualification.

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## **DEDICATION**

To my mother.

## **ABSTRACT**

In light of the advent of online pharmacies as a publicly accepted means of purchasing medical products and services, this research adopts a qualitative method of research to examine the legal challenges in the regulation of online pharmacies that dispense prescription-only medicines which may undermine the self-medicating consumer's rights. It begins by giving a general overview of the characteristics of online pharmacies and proceeds to outline the existing national and international regulatory mechanisms that may apply to them. It further investigates the dispensation of prescription-only medicines by online pharmacies in Kenya before discussing the new challenges introduced by online pharmacies, not addressed in regulation. The paper briefly discusses the attempts of the United States to regulate online pharmacies beyond brick and mortar pharmacies and concludes with suggestions on the way forward.

## **LIST OF ACRONYMS AND ABBREVIATIONS**

DEA–Drugs Enforcement Administration.

FDA–Food and Drug Administration.

FDCA–Federal Food Drug and Cosmetic Act.

ISP–Internet Service Providers.

NABP–National Association of Boards of Pharmacy.

OTC–Over-the-counter.

POM–Prescription-only medicine.

PPB–Pharmacy and Poisons Board.

U.S.– United States of America.

VIPPS- Verified Internet Pharmacy Practice Sites.

WHA–World Health Assembly.

WHO–World Health Organisation.

## **LIST OF LEGAL INSTRUMENTS**

### **Kenyan legal instruments**

Constitution of Kenya (2010).

Consumer Protection Act (Act No.46 of 2012)

Kenya Information and Communications (Consumer Protection) Regulations, 2010.

Narcotic Drugs and Psychotropic Substances (Control) Act (Act No. 4 of 1994).

Pharmacy and Poisons Act (Act No. 17 of 1956).

Pharmacy and Poisons Rules.

### **US legal instruments**

Controlled Substances Act.

Federal Food, Drug, and Cosmetic Act.

Ryan Haight Online Pharmacy Consumer Protection Act.

# CHAPTER ONE

## INTRODUCTION

### 1.1 Background of the Study

In this day and age, more of the world has access to mobile devices and the Internet than ever before. Conventional times have seen the introduction of e-commerce which has enabled the buying and selling of a wide range of services and goods, including medicines, over the Internet. Without face-to-face interactions with health professionals, consumers can now access medications from online pharmacies that were previously only available in brick and mortar pharmacy establishments.

Online pharmacies— also referred to as e-pharmacies, cyber pharmacies, Internet pharmacies or virtual pharmacies— are Internet-based vendors of medicines and health-related goods and services.<sup>1</sup> They operate through websites and/or mobile applications and may be categorised into independent Internet-only sites, online branches of brick and mortar pharmacies (click and mortar), and those representing partnership among pharmacies.<sup>2</sup> Some of the goods they sell include medical devices, herbal products, pet medicines, beauty products, over-the-counter (OTC) medicines and prescription-only medicines(POM).

Advancement in information technology, changing consumer behaviour and the accessibility of the Internet has greatly influenced the advent of online pharmacies.<sup>3</sup> By the end of September 2018, the total number of active Internet subscriptions in Kenya stood at 42.2 million and the reported number of mobile commerce transactions at 526.9 million.<sup>4</sup> With the increasing accessibility of the Internet and the vast distribution of information it facilitates, the popularity of online medicine purchase is likely to grow.

Online pharmacies benefit the consumer's healthcare experience by affording them with the advantage of convenience, ease of accessibility, greater confidentiality, competitive pricing,

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<sup>1</sup>Ekpedeme N, Arit U, Olajide A, Enitome B, 'Consumer and Community Pharmacists' Perceptions of Online Pharmacy Services in Uyo Metropolis, Nigeria', *Innovations in Pharmacy*,10(3), 2019, 1."

<sup>2</sup> Fung C, 'Controversies and legal issues of prescribing and dispensing medications using the Internet' *79(2) Mayo Clin Proc.* 2004, 188–194.

<sup>3</sup> KPMG International, *The Truth about Online Consumers: The 2017 Global Online Consumer Report*, 2017,1–40.

<sup>4</sup> Communications Authority of Kenya, *First Quarter Sector Statistics Report for The Financial Year 2018/2019*, 13 February 2019, 10.

delivery at a suitable location and efficiency by reducing the time and effort of shopping.<sup>5</sup> Unlike traditional brick and mortar pharmacies, online pharmacies have no limits on geographic proximity.<sup>6</sup> Patients with limited mobility and those that suffer from chronic conditions can benefit enormously from online pharmacies.<sup>7</sup>

Inasmuch as online pharmacies offer numerous opportunities to improve healthcare, they also present various downsides. Distance selling of medicines may facilitate possibilities of misconduct such as the improper use of data; the dispensation of poor quality, adulterated and substandard medications; illegal advertising; and the purchase and sale of POM without a valid prescription from prior medical consultation with legally recommended prescribers.

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POM include antimicrobials, antihypertensives, antidiabetics, antidepressants and narcotic analgesics.<sup>9</sup> They are potentially harmful if not used as prescribed by licensed healthcare providers. As a safety measure, a prescription from a qualified medical practitioner is required in order to purchase them. The philosophy behind a prescription is that consumers are not skilled enough to make their own choices as to whether the benefit-harm balance of prescription medicines apply to them for the treatment of specific medical diagnoses.<sup>10</sup>

The dispensing of POM without a valid prescription may facilitate drug misuse by self-medicating consumers who may acquire inappropriate medications in inappropriate quantities with no regard for side effects or interactions with other drugs that they may be taking. The choice of self-medicating consumers to bypass seeking professional medical advice is often driven by arrogance or ignorance depending on their education status, family and cultural attitudes, previous experiences with symptoms or diseases and previously used prescription medicines that are stored at home.<sup>11</sup>

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<sup>5</sup> Orizio G, Gelatti U, 'Public e-health and new scenarios in terms of risks and opportunities: a specific focus on cyber pharmacies', *Social Semiotics*, 20(1), 2010, 29–41.

<sup>6</sup> Orizio G, Merla A, Schulz P, Gelatti U, 'Quality of online pharmacies and websites selling prescription drugs: a systematic review', *J Med Internet Resources*, 13(3), 2011,74.

<sup>7</sup>Schmittiel J, Karter A, Dyer W, Parker M, Uratsu C, Chan J, Duru O, 'The comparative effectiveness of mail order pharmacy use vs. local pharmacy use on LDL-C control in new statin users', *Journal of general internal medicine*, 26(12), 2011, 1396–1402.

<sup>8</sup> Mackey T, Nayyar G, 'Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies', *Br Med Bull*, 118(1), 2016, 110–126.

<sup>9</sup> <<http://www.pharmacyboardkenya.org/beta/blog/2017/12/avoid-self-medication>> on 20 August 2019

<sup>10</sup>Aronson J, 'Medication errors: what they are, how they happen, and how to avoid them', *QJM*,102(8), 2009,513–521.

<sup>11</sup> <<http://www.pharmacyboardkenya.org/beta/blog/2017/12/avoid-self-medication>> on 20 August 2019

Assuming that consumers are well informed on the characteristics and use of medicines, proper self-medication, according to the World Health Organisation(WHO) requires that medicines used are available without prescriptions (OTC) and are considered relatively safe and effective when used as directed by a pharmacist.<sup>12</sup> While self-medicating can be a convenient practice and produce positive results, consumers that self-medicate improperly or with POM expose themselves to a plethora of risks including drug dependence, misuse of medications, incorrect self-diagnosis, delays in seeking medical advice when needed, adverse effects from the use of inappropriate medicines, masking the symptoms of a serious disease, inaccurate dosages, harmful drug interactions, incorrect manner of administration and antimicrobial resistance.<sup>13</sup>

One of the easiest POM to find online without a prescription in Kenya is Sildenafil Citrate. Better known as Viagra, the drug used to treat erectile dysfunction has been reported to be one of the most ordered drugs on Kenyan online pharmacy platforms by its manufacturer, Pfizer.<sup>14</sup> When taken with certain medicines such as “nitrates”, Viagra can lead to a sudden drop in blood pressure to unsafe levels.<sup>15</sup> The high sales of Viagra have been attributed to an online pharmacy known as “ePharmacy”.<sup>16</sup>

Besides ePharmacy, other popular online pharmacies that dispense POM in Kenya include: “MyDawa”, “Medicart”, “Livia Dawa App”, “Pharmashop”, “PharmacyDirect Kenya”, “Emart”, among others. MyDawa was the first online retailing pharmacy to be issued with a license in May 2018.<sup>17</sup>

Although these online pharmacies conveniently contribute towards the maintenance of human wellbeing, they serve an insufficiently regulated market with insufficient consumer protection. A 2011 survey of 114 WHO member states found that a majority of the responding countries (66%) had no laws that either allowed or prohibited online pharmacies

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<sup>12</sup> World Health Organization, *WHO guidelines for the regulatory assessment of medicinal products for use in self-medication*, WHO/EDM/QSM/00.1, 2000.

<sup>13</sup> —<<http://www.pharmacyboardkenya.org/beta/blog/2017/12/avoid-self-medication>> on 20 August 2019

<sup>14</sup>Saya M, ‘Viagra most ordered drug on Kenyan online pharmacy platforms’ The Star, 7 February 2019 —<<https://www.the-star.co.ke/news/2019-02-07-viagra-most-ordered-drug-on-kenyan-online-pharmacy-platforms/>> on 13 September 2019.

<sup>15</sup>—<<http://labeling.pfizer.com/ShowLabeling.aspx?id=652&section=ppi>> on 13 September

<sup>16</sup>Saya M, ‘Viagra most ordered drug on Kenyan online pharmacy platforms’ —<<https://www.the-star.co.ke/news/2019-02-07-viagra-most-ordered-drug-on-kenyan-online-pharmacy-platforms/>> .

<sup>17</sup> Odhiambo H, ‘MyDawa brand the first-ever Retail License for an e-retailing pharmacy in Kenya’ CIO East Africa, 9 May 2018 —<<https://www.cio.co.ke/mydawa-brand-the-first-ever-retail-license-for-an-e-retailing-pharmacy-in-kenya/>> on 14 February 2019.

or governed the operation of online pharmacies.<sup>18</sup> Only 7% allowed them and had a national process for certifying, accrediting, or regulating them. This dissertation will look into Kenya's position in the regulation of online pharmacies from a consumer protection perspective.

## 1.2 Statement of the Problem

Even though online pharmacies serve the same end as brick and mortar pharmacies— of making medicines available to patients— there is an unaddressed discrepancy with respect to their regulation in contrast with traditional pharmacies. Existing regulatory measures governing the pharmacy practice fail to address crucial aspects of online pharmacies and may, as a result, enable questionable dispensing practices such as the dispensing of POM to consumers without a valid prescription. If an online pharmacy allows consumers to purchase POM without asking for a prescription, significant shields are missed. Apart from the lack of a doctor's assessment, a prescription is not reviewed as required by a pharmacist. The patient diverts the two professionals that usually inform patients on the proper use and dangerous side effects of drugs.<sup>19</sup> Additionally, the buying of medications online is treated as a matter of caveat emptor as consumers are tasked with the burden of assessing the suitability of medicines before making a purchase even though they may not have the requisite knowledge and skills to do so.<sup>20</sup> In view of the characteristics of the Internet including its anonymity, its anarchic nature and the lack of physical human interaction, self-medicating consumers are more vulnerable to harm from acquiring POM online in a market lacking effective online dispensing standards and means to foster accountability.<sup>21</sup>

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<sup>18</sup>World Health Organisation, *Safety and security on the Internet: Challenges and Advances in Member States*, WHO Global Observatory for eHealth series – Volume 4, 2011, 5.

<sup>19</sup> Ashwin K, 'Online Pharmacy: An E-Strategy for Medication', *International Journal of Pharmaceutical Frontier Research*, (1), 2011, 146–158.

<sup>20</sup> WHO, *Safety and security on the Internet: Challenges and advances in Member States*, WHO, Global Observatory for eHealth series – Volume 4, 2011, 5.

<sup>21</sup> Buckley G, Gostin L, *Countering the Problem of Falsified and Substandard Drugs*, National Academies Press Washington (DC), 2013.

### **1.3 Objectives of the study**

The general objective of this study is to examine the legal challenges in the regulation of online pharmacies that dispense POM which may undermine the self-medicating consumer's rights.

In this study, the objectives will be:

- i) To examine the government's role in regulating online pharmacies.
- ii) To examine how online pharmacies in Kenya dispense medicines.
- iii) To propose appropriate recommendations to the current legal and implementation framework to prevent the illegal sale of prescription-only medications online.

### **1.4 Hypothesis**

- i) The distribution of POM without a valid prescription undermines the consumer's rights to services of a reasonable quality and the protection of their health and safety.
- ii) Poor dispensing practices by online pharmacies in Kenya encourage the distribution of POM without a valid prescription.
- iii) There are gaps in the current regulatory framework that need to be amended to discourage the online distribution of POM without a valid prescription.

### **1.5 Research Questions**

- i) What aspects of the dispensation of POM by online pharmacies are regulated by the government?
- ii) How do online pharmacies in Kenya dispense POM?
- iii) What are the gaps in the Kenya's regulatory framework with regard to the dispensation of POM by online pharmacies?

## **1.6 Justification of the Study**

Though relatively new, the e-commerce market for POM appears to have the potential for growth. Given the scarcity of literature on the legal and regulatory framework of online pharmacies in Kenya and their practices, this research will make a huge contribution to the literature on online pharmacies in Kenya which may be useful to researchers and academic scholars that want to further research on online pharmacies.

An adequate legal and regulatory framework is required if consumers are to reap the benefits of online pharmacies with confidence. This study is therefore important to consumers as it seeks to find out whether the legal and regulatory framework governing online pharmacies in Kenya is favourable and effective and; to identify its deficiencies if any.

The study will also be beneficial to policymakers and the relevant government authorities as it could inform strategies aimed at improving the welfare of the public and provide reliable information to guide them in coming up with policies that will efficiently regulate the dispensation of POM online in a manner that guarantees the safety of consumers.

## **1.7 Theoretical Framework**

### *Asymmetric information theory*

According to the asymmetric information theory, one party in a buyer-seller relationship is likely to know more about the quality of the product or services offered than the other causing a power imbalance in economic transactions. Consumers often face imbalances in economic terms, educational levels and bargaining power in comparison to retailers who are more informed about the nature of their businesses in terms of their products, characteristics and selling practices.<sup>22</sup> Because consumers are not in a position to know the relevant information, the consumer may often be unable to ascertain the quality of a product or service before a contract is concluded.<sup>23</sup>

Furthermore, under conditions where information asymmetry occurs, buyers cannot easily distinguish between high and low-quality sellers because low-quality sellers may hide their true characteristics in order to acquire unjustified profits while high-quality sellers struggle

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<sup>22</sup> United Nations Conference On Trade and Development, *United Nations Guidelines for Consumer Protection*, UNCTAD/DITC/CPLP/MISC/2016/1 22 December 2015.

<sup>23</sup> Harland D, 'Implementing The Principles of the United Nations Guidelines for Consumer Protection', *Journal of the Indian Law Institute*, 33(2), 1991, 189–245.

to convincingly convey their true quality.<sup>24</sup> Ordinarily, consumers form their preferences in the case of differentiated goods based on identifiable characteristics, their reputation, and quality. Thus, where there is information asymmetry, the basis of the consumer's decisions is likely to be distorted.

Due to the physical separation between buyers and sellers in the online environment, information asymmetry is prevalent. Information asymmetry is particularly problematic for online exchange relationships as it may give rise to hidden information. Intervention in the market in favour of the consumer is, therefore, necessary to facilitate the provision of adequate information concerning goods and services. This can be done through the establishment of the duty of online sellers to give buyers necessary information and State provision of information.

The supply of medicines differs from the supply of other goods in that the recipient usually does not know their correct use and is unable to determine their quality. The responsibility to ensure the correctness and quality of medicines, therefore, lies with pharmacists whose abilities are relied upon by the patients. Pharmacists usually have undergone the necessary training to be familiar with the medications that they sell, the guiding rules of practice and their characteristics in terms of their correct dose, common use, method of use, common interactions with other medicines or food, common side-effects and their storage requirements.<sup>25</sup> Because their knowledge in medicines is greater than that of the consumer, they are mandated to play an oversight role over their pharmacies to ensure that the quality of their service and the medicines supplied to patients are suitable. They also have the capacity to advise and answer questions from patients on how to take medicines and what reactions may occur. The information they possess should, thus, be properly managed to promote and protect the rights of consumers.

Regulation to discourage the purchase and sale of POM online without prescriptions from authorised medical practitioners would be useful in discouraging this form of information asymmetry.

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<sup>24</sup> Pavlou, P, Liang, H, Xue Y, 'Understanding and Mitigating Uncertainty in Online Exchange Relationships: A Principal-Agent Perspective', *MIS Quarterly*, 31(1), 2007, 105–136

<sup>25</sup> World Health Organization, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

## 1.8 Literature Review

Hock, Lee & Chan<sup>26</sup> took an international approach in studying the regulation of online pharmacies. Their study found that numerous regulatory authorities across the countries lacked legislation to properly regulate online pharmacies. It was established that jurisdictional limitations due to the trade in pharmaceuticals across borders and resource limitations allowed participants in the illegal trade of medicines to escape prosecution. Additionally, the lack of legislation that would mandate the cooperation of private organizations in investigations was found to impact enforcement efforts negatively. It was proposed that regulatory authorities take a holistic approach in regulating “the e-commerce of medicinal products” by implementing industry guidelines, advisories, and warnings; legislation; and enforcement mechanisms. The study was however focused on results in Europe, Asia, North America and South America. Consequently, this research seeks to focus on the regulation of online pharmacies in Kenya.

Idenya<sup>27</sup> sought to establish the extent to which online marketing had been adopted in pharmacies in Nairobi. The study found that some pharmacies offered medicines online for sale with a majority of the pharmacies in Nairobi using online marketing of medical products as a tool for providing information on goods and services. Various characteristics of the online distribution of medical products and service delivery were revealed. Organizations communicated with their consumers through SMS, emails, and online banners and telephones. The mode of payment for the products was facilitated by the availability of intangible credit facilities by use of credit cards and e-banking service providers such as M-PESA, Pesapal and PayPal. The majority of the pharmacies in the study were found to use intermediaries such as agents, brokers and retailers to link them to their clients during the process of delivering the products. While the study sheds light on some elements of online pharmacies in Kenya, the efficacy of the present consumer protection regulation concerning online pharmacies is not addressed. This dissertation will, therefore, take a step further to comprehensively address the regulation of online pharmacies in Kenya in relation to the subject of the misuse of POM.

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<sup>26</sup> Hock S, Xuan M, Chan L, 'Regulating Online Pharmacies & Medicinal Product E-Commerce', *ISPE*, 2019 <<https://ispe.org/pharmaceutical-engineering/november-december-2019/regulating-online-pharmacies-medicinal-product-e#>> on 23 November 2019.

<sup>27</sup> Idenya E, 'Adoption of E-Marketing in Pharmacies in Nairobi', Published MBA Thesis, University of Nairobi, Nairobi, 2012.

## **1.9 Research Methodology**

This research primarily adopted a qualitative method of study in gathering information. Desktop research which involved visiting library databases such as JStor and NCBI and conducting online research was employed. Secondary sources in the form of books, research papers, journals, newspapers and magazines, online articles, conference papers were also critical to this research. Primary sources such as the Constitution of Kenya, statutes and World Health Organisation reports and publications were relied upon.

## **2.0 Limitations to the Study**

Although online pharmacies exist in Kenya, barely any research has been done on the online dispensation of medicine in relation to consumer protection.

This paper was limited to desktop research and did not employ quantitative research methods such as the use of questionnaires and oral interviews due to time constraints.

## **2.1 Chapter Breakdown**

The chapter breakdown is as follows:

### *Chapter 1:*

This chapter lays the foundation of this research giving a background of how online pharmacies operate and introducing the problem. Related works authored are also be reviewed.

### *Chapter 2:*

This chapter outlines a breakdown of the relevant regulatory and institutional framework for regulating the dispensation of medicine online for analysis.

### *Chapter 3:*

This chapter discusses various topics relating to the research questions and will outline the findings of the research on the operations of online pharmacies.

### *Chapter 4:*

This chapter uncovers the gaps in controls and regulations based on the findings of the research.

### *Chapter 5:*

This chapter concludes the research. Possible strategies that may help prevent illegal trade in prescription medications on online sites will also be discussed.

## **2.2 Definition of terms**

*Brick and Mortar*: a traditional business that performs its business offline and/or sells physical products using physical agents.<sup>28</sup>

*Click and Mortar*: a non-traditional business that conducts some of their business activities online but does their primary business in the physical world.<sup>29</sup>

*Self-medication*: the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms.<sup>30</sup>

*Antimicrobials*: Drugs acting against microorganisms that cause disease such as antibiotics which act against bacteria.<sup>31</sup>

*Antihypertensives*: Drugs used to treat hypertension (high blood pressure).<sup>32</sup>

*Antidiabetics*: Drugs used in the treatment of diabetes.<sup>33</sup>

*Antidepressants*: Drugs used to relieve symptoms of depression by stimulating the mood of a depressed person.<sup>34</sup>

*Narcotic analgesics*: Pain-relieving drugs which make someone sleep or become unconscious such as opium and codeine.<sup>35</sup>

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<sup>28</sup> Mwencha P, '2016 E-Commerce Sub-Sector Assessment Report for Kenya', Kenya E-Commerce Industry Research, Working Paper No. 8, 2018,23<[https://www.researchgate.net/publication/322910347\\_2016\\_E-Commerce\\_Sub-Sector\\_Assessment\\_Report\\_for\\_Kenya](https://www.researchgate.net/publication/322910347_2016_E-Commerce_Sub-Sector_Assessment_Report_for_Kenya) on 12 September 2019.

<sup>29</sup> Mwencha P, '2016 E-Commerce Sub-Sector Assessment Report for Kenya', 23.

<sup>30</sup> World Health Organization, *The role of the pharmacist in self-care and self-medication*, Report of the 4th WHO Consultative Group on the Role of the Pharmacist, 1998, 3.

<sup>31</sup> Dictionary of Medical Terms, 4<sup>th</sup> ed.

<sup>32</sup> Dictionary of Medical Terms, 4<sup>th</sup> ed.

<sup>33</sup> Dictionary of Medical Terms, 4<sup>th</sup> ed.

<sup>34</sup> Dictionary of Medical Terms, 4<sup>th</sup> ed.

<sup>35</sup> Dictionary of Medical Terms, 4<sup>th</sup> ed.

## CHAPTER TWO

### RELEVANT REGULATIONS TO THE ONLINE DISTRIBUTION OF PRESCRIPTION ONLY MEDICINES

The ultimate aim of the regulation of the distribution of POM is to protect the recipient consumers. Consumer safety concerns surrounding online pharmacies intersect between the pharmaceutical healthcare and e-commerce policy domains.<sup>36</sup> While online consumer protection in the e-commerce sector involves protecting consumers' interests and rights as they engage in online transactions, consumer protection in the pharmaceutical industry is focused on protecting consumers against the risk of harm associated with medicines. Kenya has adopted a variety of regulatory measures directed towards enhancing consumer safety that may apply to local online pharmacies dispensing POM. This chapter outlines the key regulations and enforcement methods as they apply in Kenya to limit the health risks posed by the inappropriate distribution of POM to consumers.

#### 2.1 NATIONAL REGULATION

##### i) THE CONSTITUTION OF KENYA

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 such as pharmaceutical services.<sup>37</sup> Further, Article 46 states that consumers have the right to goods and services of reasonable quality; to the information necessary for them to gain full benefit from goods and services; to the protection of their health, safety; and to compensation for loss or injury arising from defects in goods or services.<sup>38</sup> The Article also directs Parliament to enact legislation to provide for consumer protection.<sup>39</sup> It is through this direction that the Consumer Protection Act was enacted.

##### ii) THE CONSUMER PROTECTION ACT

The Consumer Protection Act outlines provisions intended for the protection of the consumer and the prevention of unfair trade practices in consumer transactions. It spells out

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<sup>36</sup> Mackey, T, Liang B, 'Pharmaceutical digital marketing and governance: illicit actors and challenges to global patient safety and public health' 9(45), *Global Health*, 2013.

<sup>37</sup> Article 43, Constitution of Kenya (2010)

<sup>38</sup> Article 46, Constitution of Kenya (2010)

<sup>39</sup> Article 46, Constitution of Kenya (2010)

a wide range of consumers' rights concerning product distribution and service delivery—one of which is the right to have full pre-contractual information in order to make informed choices.<sup>40</sup> Suppliers are deemed to warrant that goods supplied to consumers are fit for the purpose for which they are meant.<sup>41</sup>

iii) THE KENYA INFORMATION AND COMMUNICATIONS (CONSUMER PROTECTION) REGULATIONS 2010

The Kenya Information and Communications (Consumer Protection) Regulations sets out the rights and obligations of consumers with regard to e-commerce transactions. Some of the rights of consumers under the Regulations include the right to receive clear and complete information about rates of offered goods and services and terms and conditions; protection from unfair trade practices and; the right to personal privacy and protection against unauthorized use of personal information.<sup>42</sup>

iv) THE PHARMACY AND POISONS ACT

*Establishment of the Pharmacy and Poisons Board*

Section 3 of the Pharmacy and Poisons Act establishes the Pharmacy and Poisons Board.<sup>43</sup> The Board's mandate is to protect the health of the public by regulating the pharmacy practice and the manufacture and trade in drugs and poisons and; ensuring the safety, quality and efficacy of medical products distributed and used in Kenya.<sup>44</sup>

To ensure that genuinely licensed personnel serve consumers through licensed outlets, the Board has issued all pharmacies with a health safety code which is visibly displayed at pharmacies. Consumers can send a free SMS of the code to the number "21031" to verify the registration status of a pharmaceutical outlet.<sup>45</sup> If a pharmacy is licensed, consumers will receive a message indicating registration details of the pharmacy including their location and

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<sup>40</sup> Section 31, Consumer Protection Act (Act No.46 of 2012)

<sup>41</sup> Section 5, Consumer Protection Act (Act No.46 of 2012)

<sup>42</sup> Section 3(1), Kenya Information and Communications (Consumer Protection) Regulations, 2010

<sup>43</sup> Section 3, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>44</sup>—<<https://pharmacyboardkenya.org/about-us>> on 15 September 2019

<sup>45</sup>—<<https://pharmacyboardkenya.org/blog/2017/12/be-safe-buy-medicines-from-licensed-pharmacy>> on 15 September 2019

the name of the superintendent. The premises should also display licenses issued annually by the Board for both premises and personnel and a photo of the superintending personnel along with their registration details.<sup>46</sup>

The Board conducts routine inspections and crackdowns to ensure all pharmacies are complying with rules and regulations for the pharmacy practice. One of the directorates of the Board is the Directorate of Inspectorate, Surveillance and Enforcement whose mandate is to ensure supply chain integrity through inspection of distribution outlets.<sup>47</sup>

#### *Conspicuous exhibition of name and certificate of registration*

Upon registering, a pharmacist is issued with a certificate of registration. According to Section 20 of the Act, it is unlawful to carry on the business of a pharmacist unless the name and certificate of registration of the person in control of the business are conspicuously exhibited in the premises in which the business is carried on.<sup>48</sup> A licensed seller of medicines may be required to produce their certificate of registration during the regular inspections carried out by authorised officers.<sup>49</sup>

#### *Registration of Premises*

Section 23 of the Act makes it unlawful to carry on the business of a pharmacist except in registered premises.<sup>50</sup>

#### *The classification of medicines*

The Act requires the Board to prepare a list referred to as the “Poisons List” to outline substances considered to be poisons.<sup>51</sup> The Poisons List outlines the substances which are to be treated as poisons in the Act and is set out in the Schedule to the Poisons List Confirmation Order. The poisons list consists of two parts, Part I and II.

Part I of the list consists of poisons which are not to be sold except by authorized sellers of poisons, licensed wholesale dealers and dealers in mining, agricultural or horticultural

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<sup>46</sup> –<<https://pharmacyboardkenya.org/pharmacies-crackdown>> on 15 September 2019

<sup>47</sup> Wairimu P, Khaemba C, Waihenya S, Naanyu N, Kisorio K, ‘PPB holds a sensitization training for investigating officers and ODPP personnel within Nairobi region’ PPB Magazine, 2018, 26.

<sup>48</sup> Section 20, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>49</sup> Section 47, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>50</sup> Section 23, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>51</sup> Section 25, Pharmacy and Poisons Act (Act No. 17 of 1956)

accessories.<sup>52</sup> Antibiotics, arsenic substances, alkaloids such as codeine and cocaine, among others are listed as some of the Part I poisons.

Part II poisons are sold by persons entitled to sell Part I poisons as well as by persons licensed upon making an application to the Pharmacy and Poisons Board.<sup>53</sup> Part II poisons are in common use, or likely to come into common use. Some of the poisons listed as Part II poisons include substances such as ammonia, hydrochloric acid and nitric acid.

Some Part I poisons are listed in Part II as well— only their quantities are limited. Codeine, for example, can be considered a Part II poison when contained in a substance in a proportion of less than 1.5 per cent. In limited quantities, morphine and arsenics can also be Part II poisons.

The Act allows authorized sellers of poisons to sell Part I poisons to persons in possession of a prescription of a duly qualified medical practitioner.<sup>54</sup> Sellers are required to make an entry in the “Poisons Book”, indicating the date of the sale, the name and address of the purchaser or agent, the name and quantity of poison sold, and the purpose for which it is stated by a purchaser to be required before delivering Part I poisons to the person by whom it is to be used.<sup>55</sup>

A few Part I poisons, such as codeine, are also classified as controlled substances under the Narcotic Drugs and Psychotropic Substances(Control) Act. Under the Act, possession of controlled substances is prohibited unless they are prescribed for a medical purpose.<sup>56</sup>

Generally, Part I poisons and controlled substances are POM while Part II poisons are OTC medicines.

#### *Substances exempted from sale*

Schedule I of the Act lists substances exempted from sale under the Act. These include codeine, morphine, opium, and others.

#### *Substances to be sold upon prescription*

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<sup>52</sup> Section 25(2)(a), Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>53</sup> Section 25(2)(b), Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>54</sup> Section 29(2), Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>55</sup> Section 31, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>56</sup> Section 3(3), Narcotic Drugs and Psychotropic Substances (Control) Act (Act No. 4 of 1994)

Schedule IV of the Act lists substances required to be sold only upon presenting a prescription. These include antibiotics and arsenics.

v) PHARMACY AND POISONS RULES

*Fundamental elements of a prescription*

A prescription is required to:

- a) be in writing and be signed by the person giving it with his usual signature and be dated by him;
- b) specify the address of the person giving it;
- c) specify the name and address of the person for whose treatment it is given;
- d) specify the total amount of the medicine to be supplied and;
- e) the dose to be taken— unless a preparation is to be used for external treatment only.<sup>57</sup>

*Subsequent use of a prescription*

According to the Rules, the prescription for Part I poisons should not be dispensed more than once unless the prescriber has directed that it can be dispensed a stated number of times or intervals.<sup>58</sup> Where a poison can be dispensed more than once, the name and address of the seller and the date on which the prescription was dispensed is to be noted on the prescription above the signature of the prescriber on the subsequent receipt of the prescription.<sup>59</sup>

*Retention of prescriptions*

If a prescription is meant to be dispensed only once, the prescription is to be retained and kept on the premises on which it was dispensed for 2 years so as to be readily available for inspection.<sup>60</sup>

vi) GUIDELINES FOR GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICALS

The Guidelines for Good Distribution Practices for Pharmaceuticals, published by the Board, serves as a guide to licensees regarding the distribution of drugs and poisons by retail and

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<sup>57</sup> Rule 6(5), Pharmacy and Poisons Rules

<sup>58</sup> Rule 6(6)(a), Pharmacy and Poisons Rules

<sup>59</sup> Rule 6(6)(d), Pharmacy and Poisons Rules

<sup>60</sup> Rule 6(6)(e), Pharmacy and Poisons Rules

wholesale pharmaceuticals. The guidelines provide for minimum requirements on the nature and setup of premises, licensing and operations of retailers as the final contact personnel with consumers. As to the nature and set up of premises, the guidelines state that construction of a pharmacy must be of a permanent nature.<sup>61</sup> Requirements as to the spacing, lighting and ventilation of the premises are also specified.

## **2.2 INTERNATIONAL REGULATION**

### ***Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services***

The International Pharmaceutical Federation (FIP) and the World Health Organisation (WHO) have collaborated to draw up guidelines to guide national pharmaceutical regulatory authorities in the development of their national Good Pharmacy Practice(GPP) guidelines. The guidelines set out minimum standards that member states should consider in determining the role of pharmacists in the healthcare system. In fulfilling their role in dispensing medicines, it is recommended that pharmacists be expected to assess and evaluate all paper or electronic prescriptions received, before supplying medical products to the patient and; provide advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment.<sup>62</sup>

### ***International Narcotics Control Board(INCB) guidelines for governments on preventing the illegal sale of controlled substances through the Internet.***

The INCB is an independent and quasi-judicial monitoring body for the implementation of the United Nations(UN) international drug control conventions.<sup>63</sup> The Board has drawn up guidelines to provide member states of the UN with assistance in the formulation of legislation and policies with regard to the use of the Internet to dispense and purchase internationally controlled substances.<sup>64</sup> The guidelines address POM to the extent that they are controlled substances or contain controlled substances.

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<sup>61</sup>Pharmacy and Poisons Board, *Guidelines for Good Distribution Practices for Pharmaceuticals (First Edition)*, 2006, 2–17.

<sup>62</sup> WHO, '*Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services*' WHO Technical Report Series, No. 961, 2011.

<sup>63</sup> —<<http://www.incb.org/>> on 30 September 2019

<sup>64</sup> International Narcotics Control Board, '*Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet*', 2009, 5.

Some of the recommendations by the Board are:

- i) that governments require online pharmacies that sell controlled substances within their jurisdictions be registered and obtain licences for dispensing medicines containing controlled substances;
- ii) that governments establish standards of good professional practice for the provision of pharmaceutical services on the Internet and;
- iii) that governments include provisions in their national legislation that empower the appropriate authorities to investigate and take legal action against online pharmacies that participate in the illegal sale of controlled substances such as through cooperating with Internet Service Providers(ISPs).<sup>65</sup>

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<sup>65</sup> INCB, *'Guidelines for Governments on Preventing the Illegal Sale of Internationally Controlled Substances through the Internet'*, 2009, 5.

## **CHAPTER THREE**

### **OPERATIONS OF ONLINE PHARMACIES**

The dispensation of POM involves the process of preparing and giving medicine to consumers based on a prescription.<sup>66</sup> It includes all activities undertaken between the time a prescription is presented and the time the prescribed medicine is issued to the consumer.<sup>67</sup> It involves the correct interpretation of prescription, accurate preparation and labelling of medicines, the provision of appropriate information and follow up.<sup>68</sup> As there are no physical interactions between pharmacists and patients in the online dispensing process, the adopted procedures, as well as the architecture of online pharmacy platforms, are fundamental aspects of the dispensing process as means through which the parties can interact throughout the process. This chapter aims to examine how online pharmacy websites dispense POM in contrast with brick and mortar pharmacies.

#### **3.1 THE TRADITIONAL DISPENSING PROCESS**

Purchasing POM will typically involve going to the location from which they operate. According to the WHO, pharmacies may take the following steps in the dispensing process:

##### **Step 1: Receiving and validating a prescription.**

A patient will give a prescription to a staff member at the pharmacy who should confirm their identity.<sup>69</sup>

##### **Step 2: Interpreting the prescription**

Thereafter, a pharmacist will interpret the prescription ensuring that the doses and quantities prescribed are in the normal range for the patient and taking note of the common drug-to-drug interactions.<sup>70</sup> The pharmacist can check with the prescriber if they have any doubt on

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<sup>66</sup> WHO, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

<sup>67</sup> WHO, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

<sup>68</sup> WHO, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

<sup>69</sup> WHO, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

<sup>70</sup> WHO, *Chapter 30: Ensuring good dispensing practices, Management Science for Health – Part II: Pharmaceutical Management*, 2012

what is required on a prescription for example if their handwriting is not legible. Accepted prescriptions usually are in physical form.

### **Step 3: Preparation, labelling and making the final check**

The dispenser will prepare and label the medication to be issued and check the prepared medicine against the prescription to confirm the identity of the medicine, that the medicine has been labelled appropriately and that the appropriate dose has been prescribed. Having confirmed the necessary details, the dispenser will sign the prescription.

### **Step 4: Recording information**

Afterwards, the dispenser will need to record information on the medication to be issued. There are three possibilities as to how information on medication can be recorded:

- 1) They can retain the prescription and sign and annotate the prescription with the strength and quantities dispensed and file it or enter the details into a record book.
- 2) They can return the prescription to the consumer but after details of the medication have been entered into a record book. Details to be indicated include the patient's name and age, the medicines name and strength, the amount issued, the dispenser's name and the date.
- 3) Where a computer is being used to record dispensing details, the computer program should retain the information such that it can be retrieved for future use. Information such as the stocks used in dispensing can also be recorded as a backup in case there is a need to trace any problems with medicines issued.

### **Step 5: Issuing medicine to the patient**

Finally, the dispenser will issue medicine to the patient with clear instructions and any appropriate advice about the medicine. The advice given at this point is aimed at informing the consumer on when to take the medicine, how to take the medicine and how to store the medicine. The dispenser may also give the patient warnings on the possible side-effects—ensuring that the patient understands their advice and instructions. At this stage, verbal advice may be significant where dispensers are serving illiterate persons. It may also be helpful where prescriptions are poorly labelled.

## **3.2 KEY ELEMENTS OF ONLINE PHARMACIES IN KENYA**

The dispensing process adopted by online pharmacies is somewhat similar to that of brick and mortar pharmacies but the methods by which medications are requested and received differs. To be able to extend their services, online pharmacies may facilitate connection with consumers through websites which can be accessed through an Internet search. Some of the key features of online pharmacy websites in Kenya are discussed below:

### ***3.1.1 Terms and Conditions and Privacy Policies***

An online pharmacy may have terms and conditions and a privacy policy. Terms and conditions and privacy policies govern the purchase and use of goods and services acquired from the online pharmacies and may constitute a legally binding agreement between the customer and the online pharmacy.<sup>71</sup> By visiting, viewing, accessing or using services or information on the website users are deemed to agree to be bound by the terms and conditions and are hence advised to read them. Privacy policies govern the use of data collected from users which may include information given during registration and other information such as the users' Internet Protocol(IP) address, browser type, browser version, the pages visited on the website, the time and date of visits and the time spent there.<sup>72</sup>

### ***3.1.2 Registration of customers***

To be able to make any purchases, one will need to set up an account and provide certain information about themselves.<sup>73</sup> As part of the registration process, customers will be required to provide personal details such as their name, gender, age, an account password, email address and mobile phone number.<sup>74</sup> Customer eligibility may be limited to a particular age.

### ***3.1.3 Prescription Requirement***

Ideally, an online pharmacy will not dispense any POM without a valid prescription from a licensed physician. To make an order for POM, consumers may be required to upload the scanned copy of their prescriptions.<sup>75</sup> A photo of a prescription may also be

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<sup>71</sup> –<<https://mydawa.com/terms>> on 4 November 2019

<sup>72</sup> –<[http://medicart.co.ke/Content/privacy\\_policy](http://medicart.co.ke/Content/privacy_policy)> on 4 November 2019

<sup>73</sup> –<[http://medicart.co.ke/Content/terms\\_condition](http://medicart.co.ke/Content/terms_condition)> on 2 November 2019

<sup>74</sup> –<<https://mydawa.com/terms>> on 2 November 2019.

<sup>75</sup> –<<https://mydawa.com/terms>> on 4 November 2019

accepted.<sup>76</sup> Authorized personnel will check for the validity of a prescription and either accept or reject it.<sup>77</sup>

### **3.1.4 Payment**

Accepted payment methods of online pharmacies include payment by credit cards, insurance and e-banking and m-banking service providers such as Pesapal, PayPal and M-PESA, which allows users to store money on their mobile phones in an electronic account.<sup>78</sup> Payment may also be made upon delivery.<sup>79</sup>

### **3.1.5 Delivery**

Medicines are distributed by agents or brick and mortar retailers depending on a patient's selected pick-up location.<sup>80</sup> The involved agents may be couriers such as G4S among other offline partners. An original prescription may be collected upon delivery.<sup>81</sup>

### **3.1.6 Communication with customers**

Online pharmacies communicate with customers through telephone, SMS, personal emails, and online banners.<sup>82</sup> General information may be hosted through a list of frequently asked questions (FAQs) with their answers.

### **3.1.7 Website availability**

The websites are available 24 hours every day and may only be temporarily unavailable due to maintenance, server or other technical issues.<sup>83</sup>

### **3.1.8 Location of operation and contact information**

An online pharmacy may make their telephone number, email address and physical address available on their website.<sup>84</sup>

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<sup>76</sup> —<[http://medicart.co.ke/Content/terms\\_condition](http://medicart.co.ke/Content/terms_condition)> on 2 November 2019

<sup>77</sup> —<[http://medicart.co.ke/Content/terms\\_condition](http://medicart.co.ke/Content/terms_condition)> on 2 November 2019

<sup>78</sup> Idenya E, 'Adoption of E-Marketing in Pharmacies in Nairobi', Published MBA Thesis, University of Nairobi, Nairobi, 2012.

<sup>79</sup> —<[http://medicart.co.ke/Content/terms\\_condition](http://medicart.co.ke/Content/terms_condition)> on 2 November 2019

<sup>80</sup> Idenya E, 'Adoption of E-Marketing in Pharmacies in Nairobi', Published MBA Thesis, University of Nairobi, Nairobi, 2012.

<sup>81</sup> —<[http://medicart.co.ke/Content/terms\\_condition](http://medicart.co.ke/Content/terms_condition)> on 2 November 2019

<sup>82</sup> Idenya E, 'Adoption of E-Marketing in Pharmacies in Nairobi', Published MBA Thesis, University of Nairobi, Nairobi, 2012.

<sup>83</sup> —<<https://mydawa.com/terms>> on 4 November 2019

<sup>84</sup> —<<https://mydawa.com/terms>> on 2 November 2019.

## **CHAPTER FOUR**

### **SHORTCOMINGS IN THE CURRENT REGULATORY FRAMEWORK**

The current regulatory measures for the dispensation of POM are missing innovative solutions to combat illegal practices by online pharmacies. A look at the available regulations gives the impression that legislators lacked a fundamental understanding of online pharmacies, associated risks and the potential negative effects they might have on consumers. This chapter will look into the deficiencies and challenges in the regulation of online pharmacies. It will further look into the measures adopted by the United States to regulate online pharmacies dispensing POM and to combat their illegal distribution.

#### **4.1.1 REGISTRATION AND SUPERVISION**

Under the Pharmacy and Poisons Act, a pharmacy's premises ought to be registered to operate.<sup>85</sup> Registration allows the government to monitor the activities of pharmacies to ensure that they are operating according to their legal obligations. The interpretation of "premises" from its common meaning pertains to establishments of a physical nature. It may similarly be implied from various provisions under the Pharmacy and Poisons Act and the Guidelines for Good Distribution Practices for Pharmaceuticals that the pharmacy business was intended to be carried out in physical establishments and that the provisions therein were tailor-made for them.

While e-commerce is a legal and generally accepted means of conducting business in Kenya, it is unclear whether online pharmacies are acceptable channels of conducting a pharmacy business under the Pharmacy and Poisons Act. Like other e-commerce platforms, it may seem that online pharmacies are allowed as long as they have a physical location registered according to Section 23 of the Act to store and, if click and mortar, dispense medicines.

Requiring online pharmacies to simply comply with requirements for brick and mortar pharmacies when online pharmacies can easily overcome the traditional safeguards in place because of their virtual existence may not be enough a measure to ensure consumer safety.<sup>86</sup>

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<sup>85</sup> Section 23, Pharmacy and Poisons Act (Act No. 17 of 1956)

<sup>86</sup> Levaggi R, Marcantoni C, Filippucci L, Gelatti U, 'Not a good buy: Value for money of prescription drugs sold on the Internet' 106(3) *Health Policy*, 2012, 241–245.

Besides registering pharmacy premises, there is a need for online pharmacies to be registered separately to ensure that they are expressly authorized to conduct their business online.

#### **4.1.2 INFORMATION DISCLOSURE REQUIREMENT**

A mutual awareness between pharmacists and patients about the online purchase of medicines is necessary for the avoidance of negative consequences of self-medication. Under the current legal system, there is no comprehensive law or regulation that governs the provision of prior information with respect to online transactions. According to the Consumer Protection Act, a supplier is to disclose prescribed information to the consumer before entering an Internet agreement.<sup>87</sup> The "prescribed information" that online sellers ought to disclose under the Kenya Information and Communications (Consumer Protection) Regulations are information about rates of offered goods and services and terms and conditions.<sup>88</sup> The law remains incomprehensive as it does not clearly address the need for information such as the contact information and location of the seller, the identity of personnel in charge and the main characteristics of the goods or services.

The Kenya Information and Communications (Electronic Transactions) Draft Regulations of 2016 included provisions requiring service providers to provide information on their websites on where goods and services were offered, membership of self-regulatory or accreditation bodies subscribed to and their contact details.<sup>89</sup> The Regulations have since not been adopted.

##### *i) Identity, accessibility and authentication*

Information on who someone is, where they are and what they are doing would be important for the proper regulation of online transactions. The current Internet architecture of the Internet allows for anonymity within a website. Being anonymous means a person cannot be identified by their legal name, location, false names that can be linked or provide clues to the person's legal name or location, revealing patterns of behaviour, membership to a social group, or information that indicates personal characteristics.<sup>90</sup>

The Internet is built from a set of protocols collectively referred to as the Transmission Control Protocol/Internet Protocol ("TCP/IP") which enable communication between

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<sup>87</sup> Section 31, Consumer Protection Act (Act No. 46 of 2012)

<sup>88</sup> Section 3, Kenya Information and Communications (Consumer Protection) Regulations (2010)

<sup>89</sup> Wangigi P,

<sup>90</sup> Marx G, 'What's in a Name? Some Reflections on the Sociology of Anonymity' 15(2) *The Information Society*, 1999, 99–112.

devices connected to the Internet.<sup>91</sup> This is made possible by unique protocol addresses, called Internet Protocol(IP) addresses, which are assigned to devices from which data is to be sent and devices from which it is sent. Whenever a request is made for a page to be accessed on the Internet, the devices communicate to the webserver where they are by unveiling their IP addresses, which usually identify and locate devices online to ensure that they can connect with websites that Internet users would like to reach. If access to the Internet is provided by an Internet Service Provider (ISP) that assigns IP addresses to Internet users while on the Internet and the ISP maintains records of those assignments, Internet activity can be traced back to Internet users since their general location can be uncovered.<sup>92</sup> Internet users may, however, opt to hide their IP addresses to protect their privacy while on the Internet in various ways such as by setting up a virtual private network(VPN) which masks their IP address.<sup>93</sup> Tracing back Internet activity to an individual may also be difficult where they accessed the Internet at an Internet café or through wireless local area network(WLAN) providers such as Wi-Fi.<sup>94</sup> Hence, the Internet still provides some anonymity.

Internet anonymity allows for the protection of privacy by allowing for the management of social boundaries and the protection against personal threat but may also promote illegal and harmful actions such as the illegal dispensing of POM.<sup>95</sup> The anonymity provided by the Internet puts the consumer at a disadvantaged position as they may not be able to verify the identity of the seller. While consumers are required to disclose sensitive and personal information to be served, online pharmacies may fail to reveal information to consumers such as their contact information, physical address and the identity of pharmacists in charge and any other information that would typically influence their decision to transact.<sup>96</sup> The identification and accessibility of dispensers are of significant importance in establishing consumer trust and may assist authorities in conducting investigations and holding accountable those that are found to be engaging in illegal activity, especially if such

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<sup>91</sup> Lessig L, *Code*, 2<sup>nd</sup> ed., Basic Books, New York, 2006, 43

<sup>92</sup> Lessig L, *Code*, 2<sup>nd</sup> ed., Basic Books, New York, 2006, 43

<sup>93</sup> <<https://bigbrotherwatch.org.uk/wp-content/uploads/2017/04/VPN.pdf>> on 18 November 2019.

<sup>94</sup> Lessig L, *Code*, 2<sup>nd</sup> ed., Basic Books, New York, 2006, 43

<sup>95</sup> Kang, Ruogu & Brown, Stephanie & Kiesler, Sara. (2013). Why do people seek anonymity on the Internet? Informing policy and design. Conference on Human Factors in Computing Systems – Proceedings, Paris, 2 May 2013, 2657–2666.

<sup>96</sup> Fittler A, 'Evaluating Aspects of Online Medication Safety in Long-Term Follow-Up of 136 Internet Pharmacies: Illegal Rogue Online Pharmacies Flourish and Are Long-Lived' 15(9), *J Med Internet Res*, 2013, 199.

information is given during registration as well and is verified. Being able to authenticate that the online pharmacies are registered and the information they provide is truthful can be an important tool for consumers to look out for their own safety.

*ii) Information on drugs*

The pharmacist plays a huge role in passing information on medicines to the consumer. The pharmacist can help patients make informed choices about self-medication in order to self-medicate responsibly and where necessary, refer the patients for professional medical advice.<sup>97</sup> In a face-to-face interaction between the patient and the pharmacist, the pharmacist should ask the patient the key questions and provide them with relevant information in order to properly address the condition of the patient.<sup>98</sup> The dispensing of POM online makes the role of the pharmacist more complex because of the lack of physical interaction. The establishment of means through which online pharmacists can communicate fundamental information on the characteristics of medicines to patients is of essence in equipping patients with accurate information that will enable them to make the best choices with regard to their health. Since consumers often cannot tell OTC medicines and POM apart, it should be made clear to patients where particular drugs are POM and that they cannot be bought without a valid prescription as a result. Similarly, pharmacists should be available to speak to patients by phone, email or any other means of communication in case patients need to ask any questions related to the medicines they sell, or any health-related questions.

#### **4.1.3 THE VALIDITY OF PRESCRIPTIONS**

Under the Pharmacy and Poisons Rules, a prescription is required to be in writing and be signed and dated by the person giving it. This description of a valid prescription appears to accommodate scanned copies of prescriptions and photos of prescriptions as electronic copies of prescriptions are not prohibited. However, the ability to transmit prescriptions electronically carries the risk of the reusing of a prescription which is meant to be dispensed

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<sup>97</sup> World Health Organization, *The role of the pharmacist in self-care and self-medication* Report of the 4th WHO Consultative Group on the Role of the Pharmacist, 1998.

<sup>98</sup> World Health Organization, *The role of the pharmacist in self-care and self-medication*, Report of the 4th WHO Consultative Group on the Role of the Pharmacist, 1998.

only once or the multiple sharing of a prescription to more than one online pharmacy by consumers.

#### **4.2 THE UNITED STATES' APPROACH**

The United States(US) has made an effort to adapt its regulations to accommodate the benefits of online pharmacies, while also seeking to eliminate associated risks. While each state may individually regulate pharmacies, online pharmacies, as well as brick and mortar pharmacies, are regulated at the federal level by the Food and Drug Administration(FDA) and the Drug Enforcement Administration(DEA).<sup>99</sup>Two major ways in which the U.S. has taken strides towards regulating the dispensation of POM by online pharmacies is through the National Association of Boards of Pharmacy(NABP) accreditation program and the Ryan Haight Online Consumer Protection Act.

##### *i) The National Association of Boards of Pharmacy accreditation program*

The U.S. as a member to the National Association of Boards of Pharmacy(NABP) has adopted an accreditation program for online pharmacies. The NABP is an international association aimed at ensuring the public's health and safety that has developed pharmacist competence assessment programs and accreditation programs.<sup>100</sup>

For online pharmacies in the U.S. to be regarded as legitimate, they must be registered with the NABP, besides the DEA. The NABP has developed the Verified Internet Pharmacy Practice Sites (VIPPS) accreditation program to help consumers identify online pharmacies that are out of compliance with state and federal regulations or do not meet patient safety and pharmacy practice standards, in contrast with those that do. Sites that fulfil all the legal requirements are awarded a VIPPS seal of approval, which is displayed on their websites but because the seal could be copied easily, the NABP lists both certified pharmacies and known fraudulent ones on their website.<sup>101</sup>

As part of the application for accreditation process, policies, procedures and other documentation are reviewed and a pharmacy's state license status verified. An on-site survey is also conducted.

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<sup>99</sup> United States Government Accountability Office, *Report to Congressional Committees: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad*, July 2013, 2–6.

<sup>100</sup> —<<https://nabp.pharmacy/programs/vipps/criteria-standards/>> on 12 September 2019.

<sup>101</sup> —<<https://nabp.pharmacy/programs/vipps/vipps-accredited-pharmacies-list/>> on 12 September 2019

To earn accreditation, online pharmacies must comply with state inspection and licensing requirement and demonstrate compliance with a special criterion for VIPPS accreditation which covers specific standards that online pharmacies must comply with including ensuring the patients' rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.<sup>102</sup>

*ii) The Ryan Haight Online Pharmacy Consumer Protection Act of 2008*

The Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act") was enacted in 2008 following the death of Ryan Haight, a teenager who overdosed on prescription painkillers he purchased from an online pharmacy without a valid prescription. The Ryan Haight Act makes additions and amendments to the Controlled Substances Act(CSA)— which is specifically directed towards regulating the distribution and dispensing of controlled substances that are regarded as POM.<sup>103</sup> The Ryan Haight Act aims to protect consumers by ensuring that only legitimate online pharmacies dispense controlled substances and lawfully so through the Internet.<sup>104</sup> Key aspects addressed in the Act include:

*The in-person medical examination requirement*

Controlled substances that are POM under the Federal Food, Drug, and Cosmetic Act (FDCA) are prohibited from being delivered, distributed, or dispensed by means of the Internet without a valid prescription.<sup>105</sup> The Ryan Haight Act defines a valid prescription as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of a patient."<sup>106</sup>

*Modified Registration Requirement*

The Act requires that online pharmacies be registered with the DEA in order to be authorized to dispense controlled substances online.<sup>107</sup> Even if a pharmacy is registered as a brick and

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<sup>102</sup> Gabay, M, 'Regulation of Internet Pharmacies: A Continuing Challenge' 50(8), *Hospital pharmacy*, 2015 681–682.

<sup>103</sup> Karbeg J, 'Progress in The Challenge to Regulate Online Pharmacies' 23(2), *J.L & HEALTH*, 2010, 118.

<sup>104</sup> Karbeg J, 'Progress in The Challenge to Regulate Online Pharmacies', 118.

<sup>105</sup> Schultz B, 'Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem' 16(2), *San Diego International Law Journal*, 2015, 400

<sup>106</sup> Schultz B, 'How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem', 400.

<sup>107</sup> Karbeg J, 'Progress in The Challenge to Regulate Online Pharmacies' 23(2), *J.L & HEALTH*, 2010, 118

mortar pharmacy, an additional endorsement ought to be obtained from the DEA in order to conduct business over the Internet. This requirement puts online pharmacies at an equal footing with brick and mortar pharmacies in terms of their transparency, customer service and compliance with relevant laws.<sup>108</sup> The DEA is responsible for enforcing provisions and investigating violations of the Ryan Haight Act. By requiring all Internet sites to register, the DEA can monitor online pharmacies better and can take steps to shut down those conducting illegitimate practices as soon as they are discovered and pursue criminal and civil legal action without having to investigate individual online pharmacies.<sup>109</sup>

#### *Notice and information disclosure*

To establish consumer trust, online pharmacies must prominently and clearly display a statement declaring compliance with the new regulations on their homepage. Additionally, online pharmacies must prominently display the following information on their homepages or on a directly linked page whose hyperlink is also visible on the homepage: the name and address of the pharmacy; the pharmacy's telephone number and email address; the contact information and qualifications of the pharmacist in charge; a list of the states in which the pharmacy is licensed to dispense controlled substances; a certificate of registration to distribute controlled substances; the qualifications and contact information of the person who will provide medical evaluations or issue prescriptions for controlled substances, and a statement of notice.<sup>110</sup>

#### *Reporting requirement*

Online pharmacies must also report the amount of controlled substances they distribute in a month if the amount it has distributed is above given threshold requirements.<sup>111</sup> That way, the DEA can utilize data obtained to pursue investigative leads where consumers are buying abnormally high quantities of controlled substances.<sup>112</sup>

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<sup>108</sup> Schultz B, 'Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem' 16(2), *San Diego International Law Journal*, 2015, 400

<sup>109</sup> Schultz B, 'Online Pharmacy Regulation: How the Ryan Haight Online Pharmacy Consumer Protection Act Can Help Solve an International Problem' 16(2), *San Diego International Law Journal*, 2015, 400

<sup>110</sup> <[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2009/fr0406.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf)> on 11 November 2019.

<sup>111</sup> <[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2009/fr0406.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf)> on 11 November 2019.

<sup>112</sup> Monica K, 'Down on the Pharm: The Juvenile Prescription Drug Abuse Epidemic and the Necessity of Holding Parents Criminally Liable for Making Drugs Accessible in Their Homes', 27 *J. CONTEMP. HEALTH L. & POLICY*, 2011, 426-440.

## **CHAPTER FIVE**

### **CONCLUSION AND RECOMMENDATIONS**

#### **5.1 Conclusion**

Given the absence of legislation specifically governing online pharmacies, grey areas in the current system leave room for exploitation by online pharmacies that may dispense POM without a valid prescription— which is potentially harmful to the consumer’s health and safety. This paper has considered the various duties of key players in the dispensing process. It began by looking at the regulations governing the dispensation of medicine. In doing so, the rights of consumers and the duties of key players in the pharmaceutical healthcare system including pharmacists and the Pharmacy and Poisons Board were established. The various categories of medicines, including those that should not be dispensed, and the authorities allowed to prescribe them was also outlined. The paper then discussed the dispensing process followed by brick and mortar pharmacies and proceeded to highlight the key characteristics of online pharmacies that set them apart from brick and mortar pharmacies. Considering the operations of online pharmacies and the existing regulations that apply to them, the paper further identified the gaps and challenges in controls and regulations when it comes to regulating online pharmacies and the regulatory measures adopted by the U.S. that may be emulated.

#### **5.2 Recommendations**

Arising from the findings and conclusions of this paper and within the context of its stated objectives, the following recommendations are made:

The general public should be sensitised on the illegality of purchasing POM through the Internet without a valid prescription; on the potential risks of such purchases and; on the importance of consulting a doctor in case of illness and having a prescription, instead of self-medicating.

The government should encourage cooperation among relevant authorities such as the ministry of health, the PPB, the Communications Authority of Kenya and law enforcement on issues regarding the regulation of online pharmacies in order to develop policies and conduct operational activities within a well-coordinated framework.

The government should empower the PPB or any other appropriate institution to register online pharmacies separately from brick and mortar pharmacies so that they are able to

investigate and take legal action against online pharmacies that illegally dispense POM. A mandatory inspection or accreditation framework may be included in the licensing requirement to ensure that the online pharmacies comply with set standards.

The PPB should establish standards of good professional practice for the provision of pharmaceutical services via the Internet to establish the minimum standards that online pharmacies are to meet if they are to be licensed. For instance, online pharmacies should be required to display information such as their physical address, e-mail address and telephone number identifying the physical location of the business. Like brick and mortar pharmacies, online pharmacies should be required to display the health safety code through which information identifying the superintendent pharmacist and license details can be verified by consumers— who should be made aware about the need to verify the authenticity of dispensers.

If scanned prescriptions and photos of prescriptions are to be accepted as valid prescriptions, the government should consider associated risks and adopt methods of mitigating them.

To allow swift action to be taken against illegal activities carried out through online pharmacies, the government should establish mechanisms for sharing information on suspicious transactions with competent authorities.

The government should require Internet intermediaries such as ISPs and web hosting providers including domain name registrars to cooperate in investigations and law enforcement actions against online pharmacies illegally dispensing POM and shut down websites and domains of clients engaged in illicit activities. ISPs should also be required by law to maintain information regarding the IP addresses used when accessing the Internet in order to assist in criminal investigations.

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