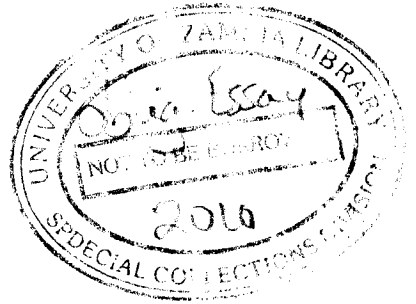


**ENFORCEMENT CHALLENGES OF PHARMACEUTICAL LEGISLATION IN
ZAMBIA**

BY



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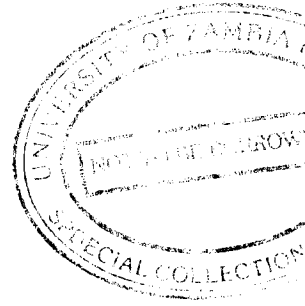
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APRIL, 2010

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ZAMBIA**

BY

SCRIVENER MULENGA



**A DISSERTATION SUBMITTED TO THE UNIVERSITY OF ZAMBIA IN
PARTIAL FULFILLMENT FOR THE AWARD OF BACHELOR OF LAWS
DEGREE**

THE UNIVERSITY OF ZAMBIA

LUSAKA

APRIL, 2010

DECLARATION

I HEREBY DECLARE THAT THIS DISSERTATION IS MY OWN ORIGINAL
WORK AND THAT TO THE BEST OF MY KNOWLEDGE NO SAME OR SIMILAR
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DATE: 9th APRIL 2010

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I recommend that this Directed Research essay prepared under my supervision by

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25041274

as partial fulfillment of the requirements for the award of Bachelor of Laws degree in the University of Zambia be accepted for examination. I have checked it carefully and I am satisfied that it fulfills the requirements relating to format as laid down in the regulations governing Directed Research essay.

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ACKNOWLEDGEMENTS

This was not an easy topic to research on, especially that there has been very little litigation on this topic. My thanks to my daughter Mwila Mulenga and my sister Vera Mulenga for the patience she exhibited during this whole ordeal.

Special Thanks to Kangwa Musole George Chisanga for inspiring and hurrying me to go to Law School.

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ABSTRACT

The importance of health to human kind cannot be overemphasized. The quest for ways of keeping human kind healthy has been mankind's pre- occupation since time immemorial. Mankind has tried all sorts of remedies to prevent sickness and therefore prevent deaths in an effort to keep human beings alive for as long as possible.

In this regard, mankind has invented so many medicines over the period he has been in existence. However, left uncontrolled, some of these remedies have been found to be harmful and in fact have caused deaths. Therefore, it has been necessary to introduce controls over these remedies, with the attendant enforcement mechanisms to minimize the chance of harmful remedies being introduced.

However, some of these controls and enforcement mechanisms affect some people's access to medicines. This presents a challenge, in that while these enforcement mechanisms are designed to ensure the safety of medicines, if enforced rigidly may also affect access to these life saving remedies.

CHAPTER 1

RATIONALE OF PHARMACEUTICAL LEGISLATION.

1.1 Introduction.

The Pharmaceutical industry is an industry that formulates and manufactures medicines and drugs for use in the treatment, prevention, and cure of human animal and plant diseases. It is today probably the most regulated of all industrial sectors. At every stage in the marketing of products there is governmental intervention.

In Zambia, regulation is achieved by application of The Pharmaceutical Act 2004.¹ This Act was assented to on 2nd September, 2004. It repealed the Pharmacy and Poisons Act 1940 and the Therapeutic Substances Act 1968. It provides for the registration and regulation of medicines intended for human consumption and also for veterinary use. It also provides for the regulation, and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied products.

The objective of Pharmaceutical laws is to protect the general public from counterfeit, bogus or adulterated, and unsafe drugs.² For example, a person who has malaria must receive medicines that have been designed, tested and found effective for malaria. History is replete with examples of questionable concoctions that were offered to treat

¹ Act No. 14 of 2004.

² Templeman v. Trafford [1881] 8 Q.B.D. 897

certain ailments. However, time and new discoveries have shown that these were useless concoctions.³

The necessity to enact a new law arises to meet new challenges posed by advancement of society. Science continues to discover new medicines and drugs that were not subject of the old Acts. It means that the old tools for control of these drugs or medicines may no longer be effective to control the newly discovered drugs after the old Act. For example, a compound called Arsenic was not on the poisons list of the Pharmacy Act of 1868 of Great Britain, and hence not controlled. However, the Pharmacy Act 1908 recognized Arsenic as a poison and was therefore a subject of control.⁴

One of the architects of the current Pharmaceutical Act, 2004 explained that it was becoming increasingly apparent that the Pharmacy and Poisons Act 1940 was outdated and therefore could not effectively deal with today's realities, brought about by advances in technology and scientific discoveries. For example, while the 1940 Act did not have provisions for control of Herbal medicines because it was not an issue then as herbal remedies were not being commercially promoted as remedies, the situation is different now. Herbal medicines are literally being forced on consumers, such that they needed to be regulated. There is also the problem of ensuring order in the industry, otherwise we

³ Patricia Barton, 'Quality of Quinine preparations in Indian Hospitals and Dispensaries.' Indian Medical Journal Volume 74, October 1939, as reported in the Article, "The Great Quinine Fraud," Social History of Alcohol and Drugs, University of Strathclyde, Glasgow. Volume 22 No. 1, 2007 at 6.

⁴ Pharmacy Act 1908 of Great Britain. Schedule A, Part 1

would have a situation where medicines are sold all over the place and in unsanitary conditions.⁵

1.2 Statement Of The Problem - The Challenge

The Pharmaceutical Act 2004 also establishes the Pharmaceutical Regulatory Authority, which replaces the Pharmacy and Poisons Board that was obtaining under the old Pharmacy and Poisons Act⁶. It is the main body that enforces the provisions of the Act. The Act stipulates the functions and powers of the Pharmaceutical Regulatory Authority.⁷ The Pharmaceutical Act 2004 repeals and replaces The Pharmacy and Poisons Act⁸ and The Therapeutic Substances Act⁹ both of which governed the pharmaceutical sector. While the Pharmaceutical Act 2004 is a progressive piece of legislation, there are still challenges as far as enforcement of provisions of the Act is concerned. An evaluation of the provisions of the Act will bring up some of these challenges. To demonstrate, the Act prohibits operating of a pharmacy without registration.¹⁰ However, no one will setup a pharmacy in a remote place like Mpulungu, for the simple reason that it is not commercially viable because a full-fledged pharmacy requires huge investment, while the returns will not be worthwhile investing so much. Although at one time in the history of this country medicines could be legally sold in general shops,¹¹ it is no longer the case, because advancement in the pharmaceutical field shows that certain medicines need to be controlled. Consequently, people have nowhere to buy regulated medicines in their

⁵ Interview : R. Kampamba, 03/11/09. Former Principal Pharmacist in the Ministry of Health and defunct Pharmacy and Poisons Board. He is widely credited with putting together the current pharmaceutical regulations.

⁶ Chapter 299 of The Laws of Zambia

⁷ Pharmaceutical Act No. 14 of 2004, ss.5 and 6

⁸ Chapter 299 of The Laws of Zambia

⁹ Chapter 310 of The Laws of Zambia

¹⁰ Pharmaceutical Act, 2004 s14

¹¹ Poisons Ordinance, Cap.98 of 1930, s.6(b)

locality. Setting up small shops would clearly be illegal although it is clear the local inhabitants need medicines. Therefore, they are forced to resort to illegal vendors, because this is a necessity of life. Regulators are therefore in a moral dilemma, either to apply the letter of the Law, or turn a blind eye. Is there an answer to this problem? Secondly, while the Law itself maybe adequate, organisational problems like inadequate staff may hamper application of the Law. Thirdly, powerful commercial interests invariably influence application of the Law by influencing Law enforcement agents to take a cursory approach to apply the law in their favour.

1.3 Research Objectives

This study attempts to explore these challenges created by advancement in the Pharmaceutical field and examine the new Pharmaceutical Act, 2004. It will look at how the Act attempts to meet these challenges and in particular the provisions for control of medicines and how they are supposed to protect members of society and improve accessibility to drugs. It looks at the enforcement mechanisms designed to ensure compliance and assesses their impact on the community in the way they access medicines. Is the impact positive or negative? Why trying to solve a problem, does the law create more problems? It also enquires on particular problems and challenges faced by the body charged to administer the Act, that is the Pharmaceutical Regulatory Authority.

1.4 Significance Of Study

The study is necessitated by the fact that the pharmaceutical field is a unique field. It has problems and processes that are peculiar to this field only. It is important that some of these problems be evaluated in their own context.

1.5 Specific Research Questions

The research is guided by such questions as why has it become necessary to enact a new Law. Who does it serve or protect and how does it do this? What are the mechanisms available under the Act for enforcing the provisions of the Act? Are they adequate? What sort of sanctions are available? How different is this Act from previous Acts? What gaps has it filled? What is the impact of this new Act? As with all positives, negatives are bound to emerge. What are the problems raised by the new law? What are the possible remedies?

1.6 Research Methodology

The study will be a desktop study as well as a field study. It will review relevant literature on the subject matter in issue, interviews with key stakeholders such as the Pharmaceutical Regulatory Authority, The Pharmaceutical Society of Zambia, Drug manufacturers, Drug importers, Pharmacy proprietors, medical and Hospital establishments, and a section of society as consumers of medicines.

1.7 Chapter Outline

The study is organized in the following way. Chapter One is the introduction and rationale behind the Pharmacy Act. Chapter Two examines the history of pharmaceutical regulation in Zambia, analyzing the gaps in the legislation as they arose and how these gaps have been filled. Chapter Three will analyse the provisions of Act. Chapter Four looks at the implementation and enforcement mechanisms available under the Act. Chapter Five analyses the probable failures and successes of the Act. Chapter Six is the General Conclusion

1.8 Rationale Of Pharmaceutical Legislation

The preamble to the Pharmaceutical Act 2004 says:

‘An Act to establish the Pharmaceutical Regulatory Authority and to define its functions; to provide for the registration and regulation of pharmacies; to provide for the registration and regulation of medicines intended for human use and for animal use; to provide for the regulation and control of medicines, herbal medicines and allied substances; to provide for the regulation and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances; to repeal the Pharmacy and Poisons Act, 1940 and the Therapeutic Substances Act, 1968; and to provide for matters connected with or incidental to the foregoing.’

It is quite clear that this Act¹² seeks to regulate or control the various facets of the pharmaceutical field.

Any person who is harmed or affected by the actions of others may seek remedies by private action in tort in the courts of Law. In *Donoghue v. Stevenson*¹³ the plaintiff had partially consumed the adulterated ginger beer which caused her a bout of gastro enteritis leading to her being hospitalized. In addition, the sight of the snail caused her shock. In this jurisdiction, similar cases include *Zambia Breweries PLC v. Mwanza*¹⁴ and *Continental Restaurant and Casino v. Chulu*.¹⁵ In *Mwanza*, the plaintiff found a dead lizard in the bottle of castle lager after drinking half its contents. In *Chulu*, the plaintiff was served with some mushroom soup. While she was taking it, she felt something hard

¹² The Pharmaceutical Act, No. 14, 2004

¹³ *Donoghue v. Stevenson* [1932] A.C. 562

¹⁴ *Zambia Breweries Plc v. Mwanza* (2001) Z.R. 12

¹⁵ *Continental Restaurant v. Chulu* (2000) Z.R. 128

in her mouth, which later turned out to be a cockroach. In all these cases, the plaintiffs were able to recover damages.

In the United States of America, the rationale for regulation was articulated by a member of the 49th Congress (1885):

In ordinary cases the consumer may be left to his own intelligence to protect himself against impositions. By the exercise of a reasonable degree of caution, he can protect himself from frauds in under-weight and in under-measure. If he can not detect a paper-soled shoe on inspection he detects it in the wearing of it, and in one way or another he can impose a penalty upon the fraudulent vendor. As a general rule the doctrine of *laissez faire* can be applied. Not so with many of the adulterations of food. Scientific inspection is needed to detect the fraud, and scientific inspection is beyond the reach of the ordinary consumer. In such cases, the Government should intervene.¹⁶

To augment the efforts of private action, and to help those who cannot afford to commence private proceedings and to ensure orderliness in the sector, the state enacts laws to regulate the pharmaceutical sector. While the State has an obligation to ensure the freedoms and rights of citizens, it also has a duty to ensure that these rights do not infringe on the rights of others. In furtherance of this ideal, various statutes that are designed to protect society and to ensure order, have been enacted. For example, we have The Road Traffic Act¹⁷, which ensures the safety of road users and other members of the public. We also have the Environmental Protection and Pollution Control Act,¹⁸ which deals with environmental protection. We also have the Penal Code,¹⁹ which criminalises certain kinds of behaviour. The Pharmaceutical Act, 2004 is one such statute, designed to protect members of the public and ensure orderliness.

¹⁶ Congressional record, 49th Congress, 1st Session pp. 5040-41

¹⁷ Road Traffic Act, No.11 of 2002

¹⁸ The Environmental Protection and Pollution Control Act, Cap.204

¹⁹ The Penal Code Cap 87

1.9 Philosophical Roots.

In pre-legal society before society evolved to the present level, injury to someone or to their interests was resolved using self-help measures. The injured person had to exact revenge or satisfaction on their own or with the help of friends, acquaintances and kinsmen. Later on, as society developed, it was realized that taking matters into their own hands in fact threatened the general peace and security of society. They, therefore, had to find a better way to ensure society's *general security*. Society needed to be secure against all that conduct that threatened its existence. In Pound's opinion, this was the paramount social interest on which satisfaction of all other claims and interests rested, since the satisfaction of all other claims need a minimum of social stability and order.²⁰

A number of writers, among them Thomas Hobbes, John Locke and Jean Jacques Rousseau, have mentioned the idea of the general security.²¹ This is the idea where men come together in society, each surrendering their individual freedoms in return for the general will, or the general security.

Five major interests are involved in the general security. These are first, general safety; second, public health; third, peace and order; fourth, security of transactions; and fifth, security of acquisitions.²² The general safety is synonymous with public safety.

Therefore, society had to organize itself in some way in order to ensure this public safety.

²⁰ Pound, Social interests; 3 Jurisprudence, discussed in Julius Stone, Social Dimensions of Law and Justice (London: Stevens and Sons Limited. 1966) , 278

²¹ Anyangwe, Introduction to Human Rights and International Humanitarian Law (UNZA press 2004) , 12

²² Pound, 3 Jurisprudence

In America, we see the police power introduced in the American constitution,²³ while in England we saw the creation of a police force. This train also brought laws dealing with safety in factories, houses, food and drugs. This was largely a result of new conditions brought about by the industrial revolution.²⁴ These police powers are subject only to constitutions, that is, the rights the citizens reserve to themselves.²⁵ Police power is one of the fundamental powers of the state. It is widespread and inclusive. In an American case of *Commonwealth v. Payne medicine Company*,²⁶ it was stated:

“The police power of a state is far-reaching and in large measure undefined. Generally speaking, it may be invoked to control and regulate, or even prohibit the doing of anything that concerns the health, lives, morals, good order, and general welfare of the community.”

Public health as a component of the general security is most visible in regulatory and preventive legislation.²⁷ We see this reflected in legislation like factory legislation,²⁸ where certain provisions deal with cleanliness, overcrowding, and general ventilation.²⁹ We also have building regulations, which are aimed at securing minimum health conditions. For example, relevant authorities must approve building plans before construction can commence.³⁰ The Pharmaceutical Act, 2004 falls into this category. A look at similar provisions of pharmaceutical regulation in other jurisdictions will help sharpen understanding of the rationale of the Pharmaceutical Act. In the state of Texas in the United States of America, we get:

²³ 10th Amendment to the United States Constitution

²⁴ Pound, 3 Jurisprudence

²⁵ In Zambia, we have Part III of the constitution.

²⁶ *Commonwealth v. Payne Medicine Company* (1910) 138 Ky. 164, 127 S.W.760

²⁷ Stone, *Social Dimensions of Law and Justice*, 291

²⁸ Factories Act, Cap 441

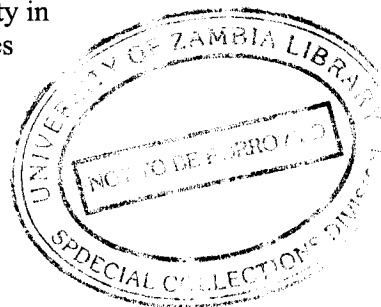
²⁹ Factories Act Cap. 441, ss.19,20 and 21

³⁰ Local Government Act Cap.281, s.61

The Texas State Board of Pharmacy seeks to protect the public through enforcement, however current statutory constraints do not permit the Board to address emerging enforcement needs created by changes and advancements in the pharmacy industry. Industry forces create an evolving pharmacy environment requiring enforcement measures responsive to these changes. To continue protecting the public from unsafe pharmacy practices, the Board's statutory enforcement authority must also change to address new threats to public safety. The ability to sanction licensees and the range of disciplinary penalties available should enable the Board to address these new enforcement challenges and protect the public. To ensure adequate public health and safety in pharmaceutical care, the Board should be able to hold its licensees accountable for safe practices.³¹

And from California, we have this excerpt:

4001.1. Protection of the Public is Board's Highest Priority
Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.³²



In conclusion, it is therefore clear from the history of the pharmaceutical field, as well as legislation that has been enacted in various jurisdictions, that the rationale for pharmaceutical legislation is the protection of the safety and welfare of the human being. Safety is paramount, and therefore each society has enacted laws that will protect its people from misguided entrepreneurs and businesspersons eager to make quick profits, without caring about the welfare and safety of members of the public. Finally, there is the problem of order, to ensure that the pharmaceutical field is conducted in an orderly manner.

³¹ Texas State Board of Pharmacy, Sunset staff report. February 2004 Issue 2 at 1. This accords with Mr. Kampamba's statement, note 9

³² California Business and Professions Code, Cap. 9, Art 1

CHAPTER 2

HISTORY OF PHARMACEUTICAL REGULATION IN ZAMBIA

Drug regulatory agencies nowadays play a key role in ensuring that medicines available for use are safe and effective. As we will see later in this chapter, events in history necessitated the introduction of drug regulatory systems. We need to look at history to understand what created the need for legislation in this field in the first place.

Industrialisation, and consequently urbanization, brought huge numbers of people together. Without planning, living conditions were appalling, and the daily struggle to ensure multitudes of people were fed led to suppliers of food supplying food that was not fit for consumption. The attendant diseases meant that medical remedies had to be supplied. However, many of these preparations were not safe, leading to several tragedies. A case in point where these problems have been recorded are the United States and Britain. In these societies, drug regulation started much earlier owing to early urbanisation, while in Zambia, a cursory attempt to regulate medicines was only made in 1921.³³

2.1 REGULATION IN THE UNITED STATES.³⁴

Food and drug regulation in the United States had its roots in the late nineteenth century. The quality of drugs and foods was virtually unregulated until the early 1900s. Around that time, food processing industries emerged to process foods for urban consumers. In an

³³ Northern Rhodesia Proclamation No. 21 of 1921

³⁴ Law, Marc. "History of Food and Drug Regulation in the United States". EH.Net Encyclopedia, edited by Robert Whaples. October 11, 2004. URL <http://eh.net/encyclopedia/article/Law.Food.and.Drug.Regulation> accessed on December 27, 2009

attempt to improve conditions and safeguard the health and welfare of people, various attempts to regulate food processing were made. At that time, Upton Sinclair published the novel, “The Jungle,” intended as a study of the lives of immigrant workers in the Chicago stockyards. People were incensed by his descriptions of the conditions that Congress passed a law to help regulate the production of food and, at the same time, drugs. This law was the original Food Drug and Cosmetic Act.³⁵

Eventually a dramatic tragedy, the Sulfanilamide tragedy, facilitated the passage of stronger laws, namely, the Food, Drugs and Cosmetics Act of 1938.³⁶ In 1937, a Tennessee drug company, began to market a liquid sulfa drug called Elixir Sulfanilamide. Unfortunately, the solvent in this drug was a highly toxic variant of antifreeze. As a result, over one hundred people died from taking this drug. This is what facilitated the passing of a new law.³⁷ Additionally, the new law required that drugs be marketed with adequate directions for safe use.³⁸

Yet another tragedy, the Thalidomide tragedy of the 1950s led to the 1962 Kefauver-Harris Amendments, which required proof that drugs are both safe and effective before marketing them. A drug tragedy in Europe, that caused the births of thousands of deformed infants whose mothers had taken the new sedative thalidomide, focused public attention on pending U.S. legislation to tighten controls in the Federal Food, Drug, and Cosmetic Act. It required sponsors of the Drug to send pre-clinical data to the FDA prior

³⁵ *ibid*

³⁶ *ibid*

³⁷ History of Pharmaceutical Medicine. www.drugstudy.md/resource9.html accessed on December 23, 2009

³⁸ Seidman, L. and Warren, N., Pharmaceutical Regulation in The United States: History and a Case study. www.bio-link.org/GMP/KELPOST.html. Accessed on December 27, 2009

to beginning phase one study, as well as obtaining Informed Consent prior to placing a person in a trial. It also required sponsors to report all findings to the FDA. It was recognized that no drug is truly safe unless it is also effective, and effectiveness was required to be established prior to marketing.³⁹

2.2 REGULATION IN ENGLAND.⁴⁰

2.2.1 The origins of control

Medicines available before the nineteenth century varied from harmless flavoured waters to dangerous poisons. Yet until the mid-1800s their supply was unregulated. In the late 1840s public concern emerged about the unrestricted availability of poisons. Large numbers of deaths resulting from poisoning were reported. Many solutions to the problem were proposed, including a total ban on its retail sale.

2.2.2 The Arsenic Act 1851

These formed the basis of the Arsenic Act 1851. For the first time retail sales of poisons were to be restricted.⁴¹

In the late 1850s more high profile poisoning cases raised calls for greater control over the sale of poisons. In May 1868, a bill produced by the Pharmaceutical Society was introduced in the House of Lords. An attempt to limit the supply of powerful drugs, especially narcotics, to prescription only was defeated because of powerful interests in the House of Lords who did not want to see narcotics controlled. The position of the Pharmaceutical Society was that the most effective safeguard in the supply of

³⁹ *ibid*

⁴⁰ British Society for the History of Pharmacy, The evolution of pharmacy Theme E, Sheet 1

⁴¹ *ibid*

poisons to the public was to restrict their sale to pharmaceutical chemists, who would be able to exercise their professional judgment.⁴²

2.2.3 The expansion of control

With enactment of the Pharmacy and Poisons Act 1868 the Pharmaceutical Society was granted powers to deem a substance a poison, to decide which substances should be available for sale, and who should be allowed to become both authorised and listed sellers of poisons. The Pharmacy Act 1908 gave pharmacists further responsibilities in relation to the control of poisons. The purchaser of opiates had to be known to the seller, and that an entry be made in the Poisons Register.

2.2.4 The emergence of new substances

New inventions of potent medicines, including barbiturates and digitalis, necessitated some revision to poisons legislation. The result was the Pharmacy and Poisons Act 1933. It contained a Fourth Schedule, which listed poisons which could only be sold to the public in accordance with a prescription given by a doctor, dentist or veterinary surgeon. There still remained concerns about the content of many medicines sold by retail. The Food and Drugs Act 1938 made it illegal for a person to sell a drug labeled in a misleading way. It also became an offence to publish an advertisement, which was misleading. Medicines were still not required to disclose their composition, provided the appropriate medicine stamp was fixed to each container. This practice ended only with passage of the Pharmacy and Medicines Act 1941.⁴³

⁴² *ibid*

⁴³ *ibid*

2.2.5 New kinds of harmful substances

By the 1920s there existed a number of substances for medicinal use which were neither poisons nor dangerous drugs. The Therapeutic Substances Act 1925 regulated by licence the manufacture, but not the sale, of a limited number of products, the purity or potency of which could not be adequately controlled by chemical means. Such products included vaccines, and insulin. It was not considered necessary at first to restrict the supply of these substances, but the introduction of penicillin and other antibiotics, and the potential for misuse meant that regulation of their manufacture, and sale had to be addressed. The Penicillin Act 1947 and later the Therapeutic Substances (Prevention of Misuse) Act of 1953, recognised that antibiotics were substances ‘capable of causing danger to the health of the community if used without proper safeguards’. These permitted their supply to the public only by medical practitioners, or from pharmacies on prescription. They were replaced by the Therapeutic Substances Act 1956, which brought the control of both the manufacture and the supply of therapeutic substances under a single statute.

2.2.6 Rationalisation of control

The Medicines Act 1968 consolidated the patchwork of legislation concerning the regulation of medicines. However, it did not include herbal medicines and foods with vague medicinal claims.⁴⁴

2.3 REGULATION IN ZAMBIA

Regulation in Zambia benefitted by drawing on the experiences of those countries which were more experienced in drug regulatory issues. As a matter of fact, most of the

⁴⁴ *ibid*

provisions that found their way into Zambian pharmaceutical laws were copied from the British statute books.⁴⁵

Although the first Chemist's shop was set up in Livingstone in 1905,⁴⁶ medicines could be sold at any General Trading Store. Specific legislation relating to pharmaceuticals, medicines or poisons first appeared on the statute books of this territory in the year 1921.⁴⁷ In terms of section 3 of the Ordinance, sale or making of any poison was restricted to medical practitioners, licensed apothecary, chemist or druggist.⁴⁸ However, the Governor of the territory could grant permission to any holder of general dealer's license to possess and sell patented medicines.⁴⁹ Compounding of medicines was left to professionally qualified Pharmacists, Apothecaries, Chemists, Druggists, and Doctors.

The Governor was clothed with many powers. He could make rules prohibiting the sale of patent medicines and substances of similar nature, regulating the grant and cancellation of permission to possess or sell medicines and poisons and also regulate the making and sale of medicines, patent medicines, poisons and substances of similar nature.

This Ordinance was a very short Ordinance.⁵⁰ It only had ten sections. This reflects the simplicity with which this field was viewed at that time. This may also reflect the state of the art at that time. At that time, such legislation was not necessary.

⁴⁵ The Poisons Ordinance No. 21 of 1921 was largely a replica of the Pharmacy Act, 1908 of Great Britain. Ordinance No. 38 of 1940 of Northern Rhodesia was largely a reproduction of the Pharmacy and Poisons Act, 1933 of Great Britain.

⁴⁶ Gann, *The Birth of a plural society*. (Manchester University Press, 1958) at 165, 166

⁴⁷ Northern Rhodesia Proclamation No. 21 of 1921. This proclamation later became Poisons Ordinance, Cap 98 of 1930

⁴⁸ Poisons Ordinance, Cap. 98 of 1930, s.3.

⁴⁹ Poisons Ordinance, Cap.98 of 1930, s.6(b)

⁵⁰ Poisons Ordinance, Cap. 98 of 1930

Comprehensive treatment of pharmaceutical legislation in this country, then Northern Rhodesia, took place by way of enactment of a new statute in 1940. This was the Pharmacy and Poisons ordinance number 38 of 1940. It repealed and replaced the Poisons Ordinance of 1921.⁵¹ This statute was practically handed down from our colonial masters, who had had the benefit of experience of filling gaps in the legislation of the motherland.⁵² This statute widened the scope of pharmaceutical regulation and introduced several safeguards.

Another safeguard introduced was the requirement to publish the names of registered pharmacists in the *Gazette* so that members of the public could be aware.⁵³ A poisons list was to be prepared under the Ordinance⁵⁴ and was a further safeguard to the public, as all poisons or medicines falling onto the list could not be supplied anyhow, but only under *prescription issued by a medical practitioner. This meant that only safe amounts of the medicine could be given out, which may not be the case if it was given by an unqualified person.*

Further safeguards were the requirement that all medicines should meet certain standards, in this case standards set by the British Pharmacopoea and the British Pharmaceutical Codex, which are professional reference books.⁵⁵

The Pharmacy and Poisons Ordinance No. 38 of 1940 remained largely unchanged, for a long time until the enactment of the Pharmaceutical Act, 2004 except for the removal of

⁵¹ Pharmacy and Poisons Ordinance No. 38 of 1940, s.37

⁵² Cap. 92 of the Laws of Nyasaland 1942 has a striking similarity to Ordinance No. 38 of 1940.

⁵³ Pharmacy and Poisons Ordinance No. 38 of 1940, s.14

⁵⁴ Pharmacy and Poisons Ordinance No. 38 of 1940, s.20

⁵⁵ Pharmacy and Poisons Ordinance No. 38 of 1940, s.33(1)

certain sections relating to registration of Pharmacists, which powers were transferred to the Medical Council of Zambia.⁵⁶

Further changes over the years occurred by way of subsidiary legislation. There were periodic additions to the poisons list created under section 20 (section 11 of the revised Act). For example, in 1985, Nalidixic Acid, a new compound, was added to the poisons list.⁵⁷ Later, it was discovered that there were substances that were not strictly poisons and hence did not fall under the control of The Pharmacy and Poisons Act, but were therapeutic in nature. Misuse of these substances could lead to undesirable effects. Therefore, The Therapeutic Substances Act, 1968⁵⁸ was enacted to control these substances.

Yet another Act that augmented the Pharmacy and Poisons Act was the Food and Drugs Act,⁵⁹ which was meant to plug some gaps left by The Pharmacy and Poisons Act. For instance, it covered such areas like prohibiting sale of adulterated drugs, and preparation of these drugs and insanitary conditions.⁶⁰

Act No. 14 of 2004,⁶¹ which is the current Act applicable,⁶² continued with the spirit of better control of the medicines and poisons. It has consolidated the Laws and regulations already in existence like the Pharmacy and Poisons Act, 1940, the Food and Drugs Act, and the Therapeutic Substances Act, 1968 and also plugged some gaps discovered over the years. To start with, it gave the Pharmaceutical Regulatory Authority, the executive body under the Act, more functions unlike under the previous Act. For example, herbal

⁵⁶ Medical and Allied Professions Act, Cap. 297, s. 16

⁵⁷ Statutory Instrument No. 61 of 1985

⁵⁸ Therapeutic Substances Act, 1968, later became Cap. 310 controlled vaccines and seras

⁵⁹ Food and Drugs Act, Cap. 303

⁶⁰ Food and Drugs Act, Cap. 303, ss.8,12

⁶¹ Pharmaceutical Act, 2004

⁶² Commenced application on 12th November, 2004 on the Authority of Pharmaceutical Act, 2004, s.1 and Statutory Instrument No. 94 of 2004

medicines became a subject of control.⁶³ Clinical trials also came under its control.⁶⁴ The Authority was also clothed with power to recall any medicine, herbal medicine or allied product from circulation if it became desirable to do so.⁶⁵

Other areas also became subject to control under the new Act. This included making it an offence to supply counterfeit medicines,⁶⁶ expired drugs,⁶⁷ and deceptive labeling.⁶⁸

⁶³ Pharmaceutical Act, 2004, s.5(1)(a)

⁶⁴ Pharmaceutical Act, 2004, s.5(1)(g)

⁶⁵ Pharmaceutical Act, 2004, s.7

⁶⁶ Pharmaceutical Act, 2004, s.33(1)

⁶⁷ Pharmaceutical Act, 2004, s.34(1)

⁶⁸ Pharmaceutical Act, 2004, s.35(1)

CHAPTER 3

SALIENT PROVISIONS OF THE PHARMACEUTICAL ACT.

The general purpose of pharmaceutical regulation is protection of members of the public.⁶⁹ In order to prosecute this mandate, the Pharmaceutical Act, 2004 is divided into twelve parts. Out of these, eleven contain substantive provisions of the law and one part contains schedules. In order to understand the applications of these provisions, we can also group the provisions into another framework divided into preliminary provisions, establishment provisions, Consumer protection provisions, prohibitions, and exemptions.

3.1 PRELIMINARIES

Part I has three sections only. The first section is the short title and commencement, while the second one is about interpretations of major terms found in the Act. It gives the meaning of the terms or words used in the Act, within the context of the Act. The third section clarifies the application of the Act. In terms of section 3, the Act does not apply to a traditional health practitioner practicing traditional medicine in a traditional setting.⁷⁰

3.2 ESTABLISHMENT

Part II has eight sections. This part is about the Pharmaceutical Regulatory Authority, the body established under the Act to administer the Act. It sets out its powers, functions, what constitutes the board and other organs of the board.

⁶⁹ Pharmaceutical Society of Great Britain v. White [1901] 1 QB 601

⁷⁰ Pharmaceutical Act 2004, s.3(1)

The Pharmaceutical Regulatory Authority is established under section 4 of the Act. It shall be a body corporate, with perpetual succession and a common seal, capable of suing and being sued in its corporate name, with powers to do what a body corporate might do or perform, but subject to provisions of the Pharmaceutical Act.⁷¹

The functions of the Authority include registering of medicines and allied substances and general regulation of the industry.⁷²

The Authority may recall medicine, herbal medicine or allied substances from circulation. The Authority may, by notice in writing, direct such person to return such medicine, herbal medicine or allied substance or direct the destruction of such medicine, herbal medicine.⁷³

The Act also makes provision for establishment of a medicine committee. The functions of the medicines committee are to advise the Board on licensing of medicines or medicinal products; monitoring the advertisements and promotion of medicines, herbal medicines and allied substances; monitoring standards relating to medicines, herbal medicines and allied substances; monitoring the conduct of clinical trials and animal clinical tests; and any other matter referred to it by the Board.⁷⁴

3.3 CONSUMER PROTECTION

Part III of the Act makes provisions for management of Pharmacies. No person other than a registered pharmacist can carry on, either on their own behalf or on behalf of another

⁷¹ Pharmaceutical Act 2004, s.4(1)

⁷² Pharmaceutical Act, 2004, s.5(1)

⁷³ Pharmaceutical Act, 2004, s.7 as read together with s.5(f)

⁷⁴ Pharmaceutical Act, 2004, s.9(3)

person the business of a pharmacist. In *Pharmaceutical Society of Great Britain v. White*⁷⁵ it was held that the purpose of pharmaceutical laws is to ensure protection for consumers. It was further held that every shop must have a registered pharmacist to supervise the sale of poisons, otherwise, a registered pharmacist may own or run a string of pharmacies and yet not be able to supervise all of them adequately, thus exposing consumers to danger of being sold wrong medicines. Pharmacists are equipped with the knowledge of poisons and medicines and therefore ensure that consumers receive safe medicines and the correct dosage. The meaning of supervision was considered in *Roberts v. Littlewoods Mail Order Stores Limited*.⁷⁶ It was held that supervision meant active supervision. It is not enough to sit in another room, out of earshot and out of view. No person shall procure, supply, package, label, prepare, admix, compound, sell, or dispense any medicine, allied substance or supply any poison; or assure quality of any medicine in practice; no person shall assume, take or exhibit or in any way make or use any title, emblem description or addition reasonably calculated to suggest that that person is a registered pharmacist.⁷⁷

A person, both natural and juridical who wishes to operate a pharmacy is required to apply for and secure a pharmacy registration certificate.⁷⁸ This is designed to ensure that only suitable premises manned by qualified personnel are allowed to operate, in order to ensure the safety of medicines supplied to the public.

⁷⁵ Supra, note 1 at 605

⁷⁶ *Roberts v. Littlewoods Mail Order Store Limited* [1943] 1 KB 269

⁷⁷ Pharmaceutical Act, 2004, s.12(1)

⁷⁸ Pharmaceutical Act, 2004, s.13(1)

This part admits one exception. Although ideally a hospital pharmacy is supposed to be managed by a registered pharmacist, the Minister may, on recommendation of the Authority, by regulations authorise the operation of a hospital pharmacy by a pharmacy technician or such other person with a recognised health related qualification and registered with the relevant registration body as the Authority may determine, but always under the supervision of a pharmacist.⁷⁹ However, this position is difficult to reconcile with the British case of *Roberts v. Littlewoods Mail Order Store* above, which held that supervision means active supervision on the premises all the time, within view and earshot.

In consultation with the Society (the Pharmaceutical Society of Zambia) and on the recommendation of the Authority, the Minister may, by regulation determine standards for the practice of pharmacy in pharmacies and hospital pharmacies.

Part VII is new area. It makes provisions for clinical trials in humans and also the testing of medicines on animals. It introduces licencing requirements for clinical trials and animal tests and prescribes conditions that must be met for a licence to be granted.⁸⁰

Part IX establishes the National Drug Quality Control Laboratory. The purpose of the Laboratory shall be, *inter alia*, to verify the safety, quality, efficacy of medicines, herbal medicines and allied substances which are manufactured or imported into this country

⁷⁹ Pharmaceutical Act, 2004, s.17(1).

⁸⁰ Pharmaceutical Act, 2004, ss.49,50

and also analyse and conduct research on medicines, herbal medicines and allied substances.⁸¹

Part X is on inspections. Inspections are a necessary tool to ensure compliance to provisions of the Act. This part gives the Authority the power to appoint inspectors whose duty is to monitor, inspect, and enforce provisions of the Pharmaceutical Act. It also sets out the powers of the inspectors so appointed.⁸²

Part XI contains general provisions. Some of these provisions necessary for our purposes include the power to authorise breaking of a patent to allow local manufacture of generic formulations of medicines in times of national health disaster to mitigate the disaster.⁸³

3.4 PROHIBITIONS

No person is allowed to operate a pharmacy except under the authority of a Pharmacy registration certificate issued under section thirteen.⁸⁴

No manufacturer, wholesale dealer, importer or distributor shall manufacture, act as a wholesale dealer, import or distribute, any medicines or allied substances unless under a licence issued under this part.⁸⁵ Elaborate requirements and conditions are laid down for grant of licences for manufacturing,⁸⁶ wholesale dealing,⁸⁷ and import or export licences.⁸⁸ There are exceptions to this provision of obtaining licences. A person may

⁸¹ Pharmaceutical Act, 2004, ss.57-58

⁸² Pharmaceutical Act, 2004, ss.59-60

⁸³ Pharmaceutical Act, 2004, s.61A

⁸⁴ Pharmaceutical Act, 2004, s.14(1)

⁸⁵ Pharmaceutical Act, 2004, s.20(1)

⁸⁶ Pharmaceutical Act, 2004, s.21

⁸⁷ Pharmaceutical Act, 2004, s.22

⁸⁸ Pharmaceutical Act, 2004, s.23

import medicines for their own use, but the amount imported shall not exceed one year's supply.⁸⁹ Exemptions from licencing requirements are also available in respect of medicines supplied by duly qualified medical practitioners, dentists, veterinary surgeons, registered nurse and registered midwife in the ordinary course of practice; or when supplied by any employee of the government in the course of their duties; or any hospital, dispensary or similar institution exempted by the minister, on the recommendation of the Authority, by statutory order.⁹⁰

This part also expressly prohibits the manufacture, import, export, distribution or sale of substandard, counterfeit or adulterated medicines or allied substances.⁹¹ Supply or sell of expired medicine or allied substances is also prohibited.⁹² Provisions are also made in respect of labeling of medicines and allied substances.⁹³

Part V enshrines the requirement to register medicines, herbal medicines and allied substances. The Authority is required to maintain a register of medicines, divided in categories under which they should be dispensed. These are prescription only medicine; pharmacy medicine; and general sale medicine.⁹⁴ In addition, the Authority may cancel a product licence issued under these regulations for certain breaches.⁹⁵ For example, a product licence may be withdrawn if a licence holder manufactures medicine that does not satisfy the required standards prescribed for that medicine.⁹⁶

⁸⁹ Pharmaceutical Act, 2004, s.20(2)

⁹⁰ Pharmaceutical Act, 2004, s.31

⁹¹ Pharmaceutical Act, 2004, s.33(1). This was mostly controlled by the Food and Drugs Act, Cap. 303.

⁹² Pharmaceutical Act, 2004, s.34(1).

⁹³ Pharmaceutical Act, 2004, s.35(1)

⁹⁴ Pharmaceutical Act, 2004, s.36

⁹⁵ Pharmaceutical Act, 2004, s.38(1)

⁹⁶ Pharmaceutical Act, 2004, s.38(1)(b)

Medicines that are required to be sold by prescription⁹⁷ shall not be supplied to any person without a prescription written by an authorised subscriber.⁹⁸

Advertising of medicines is also expected to conform to certain conditions. For example, medicines that is sold by prescription only shall not be advertised without the prior approval of the Authority.⁹⁹

The Minister is also empowered, on the recommendation of the Authority, to make regulations aimed at preventing the improper use prescription only medicines.¹⁰⁰

However, all regulations, being in nature delegated legislation, are subject to judicial review. A person affected may seek judicial review of a regulatory action in the High Court to challenge the regulation made. The challenge can be made on two grounds. First that the regulations made are *ultra vires* the main Act. In *The Attorney General v. The Local Government Electoral Commission*,¹⁰¹ the Attorney-General sought an order that regulation 10 of the Local Government Election Regulations contained in SI No 111 of 1992 and providing that all election candidates should have attained an education level of Grade VII or equivalent, was *ultra vires* the Local Government Elections Act which determined the qualifications for standing. It was held in this case that the Local Government Elections Act does not make literacy a condition for candidacy, therefore a regulation creating such a condition is *ultra vires* the Act and of no legal effect. The second instance where judicial review is available is where regulations that are made are

⁹⁷ Pharmaceutical Act, 2004, s. 41(1)

⁹⁸ Pharmaceutical Act, 2004, s. 42(1)

⁹⁹ Pharmaceutical Act, 2004, s.43(2)

¹⁰⁰ Pharmaceutical Act, 2004, s.46. However, most of these regulations are yet to be made.

¹⁰¹ *The Attorney General v. The Local Government Electoral Commission* (1990 – 1992) Z.R. 182

not reasonable or proportionate or that irrelevant considerations were taken into account before arriving at a regulation. In *Associated Provincial Picture Houses Ltd Wednesbury Corp.*¹⁰², it was held that the court is entitled to investigate the action of the local authority, with a view to seeing whether it has taken into account matters which it ought not to have taken into account or, conversely, has refused to take into account matters which it ought to take into account. Therefore, in making regulations, the Minister is enjoined to consider relevant factors. Although in this jurisdiction litigation concerning pharmaceutical laws is almost non-existent, perhaps because affected people choose not to challenge administrative actions, nevertheless it is possible to do so. In America, this occurs frequently. In the case of *Morris v. Municipal Court of City and County of San Francisco*¹⁰³, an action was brought to nullify a State Board of Pharmacy regulation, which classified hormones as dangerous drugs. The Court sustained the classification, holding that the Board had not acted arbitrarily without considering all the relevant evidence. These cases show that judicial review is available as a remedy against administrative action. Part VI continues with further provisions for regulation of herbal medicines. This is especially important because this is the first time for herbal medicines to be regulated in this country.¹⁰⁴

¹⁰² *Associated Provincial Picture Houses Ltd v Wednesbury Corp.*, [1947] 2 All ER 680; [1948] 1 KB 223.

¹⁰³ *Morris v. Municipal Court of City and County of San Francisco*. (1952) 110 Cal. App.2d 269, 242 P.2d 339

¹⁰⁴ Pharmaceutical Act, 2004, s.47

Sale of harmful cosmetics is also prohibited.¹⁰⁵ This part also contains a section that empowers the minister to make various regulations for better management of this Act, but always on the advice of the Authority.¹⁰⁶

3.5 EXEMPTIONS

In terms section 3, the Act does not apply to a traditional health practitioner practicing traditional medicine in a traditional setting.¹⁰⁷

Although ideally a hospital pharmacy is supposed to be managed by a registered pharmacist, the Minister may, authorise the operation of a hospital pharmacy by a pharmacy technician or such other person with a recognised health related qualification, but always under the supervision of a pharmacist.¹⁰⁸

Individuals may import medicines for their own use without a licence, but the amount imported must not exceed one year's supply.¹⁰⁹ Exemptions from licencing requirements also apply in respect of medicines supplied by duly qualified medical practitioners, dentists, veterinary surgeons, registered nurse and registered midwife in the ordinary course of practice; or when supplied by any employee of the government in the course of their duties; or any hospital, dispensary or similar institution exempted by the minister, on the recommendation of the Authority, by statutory order.¹¹⁰

¹⁰⁵Pharmaceutical Act, 2004, s.62, previously regulated by the Food and Drugs Act, Cap. 303

¹⁰⁶ Pharmaceutical Act, 2004, s.64

¹⁰⁷ Pharmaceutical Act 2004, s.3(1)

¹⁰⁸ Pharmaceutical Act, 2004, s.17(1)

¹⁰⁹ Pharmaceutical Act, 2004, s.20(2)

¹¹⁰ Pharmaceutical Act, 2004, s.31

CHAPTER 4

IMPLEMENTATION AND ENFORCEMENT MECHANISMS.

The fact that the pharmaceutical laws seek to regulate the practice of pharmacy, medicines and allied products implies some form of sanctions for non-compliance with the provisions of the Act. For regulation to be effective, people must know about the penalties and believe there is a reasonable probability they will be sanctioned. While some people will do the right thing, others will only do it if the consequences are harsh and real.

4.1 ENFORCEMENT

Inspectors appointed by the Authority to carry out the bulk of enforcement procedures.¹¹¹ Their duties include monitoring, inspections and where anyone is found wanting, enforcement of provisions of the Act is invoked.

Inspections are an intrusive method. They have power in terms of the law to enter the premises of a person carrying on the business of a manufacturer, seller, or distributor of any substance that is the subject of this Act and to demand the production of and inspect any books relating to the manufacture, sale, or distribution of such medicines and to inspect any stock of any such substances.¹¹² In terms of the Act, an inspector may take as many samples of the substances necessary for examination or analysis. In practice, the offending medicines or poisons are seized. However, it is not clear if the Act does allow seizure of any of these substances except under authority of a search warrant issued by a

¹¹¹ Pharmaceutical Act, 2004, s.59

¹¹² Pharmaceutical Act, 2004, s. 60(1)

magistrate.¹¹³ It is submitted this is one of the provisions meant to safeguard the privacy of persons as enshrined in the constitution by requiring a search warrant before search.¹¹⁴ This is one example of the conflict between fundamental rights of an individual and the state's need to enforce certain laws.

When a new law is enacted, especially if it restricts the rights and conduct of private citizens as enshrined in the constitution, it is attacked as being unconstitutional, and therefore void. The classic case in this jurisdiction in which legislation was attacked on grounds of unconstitutionality is *Mulundika and 7 Others v. Attorney General*.¹¹⁵ In this case, the appellants challenged the constitutionality of certain provisions of the Public Order Act which was Cap 104 then, especially section 5(4) which required any person wishing to hold a peaceful assembly to obtain a permit and contravention of which was criminalized by section 7 of same Act. The Court held that section 5(4) of the Public Order Act Cap 104 contravened articles 20 and 21 of the Constitution, and therefore null and void. The same principle applies in respect of Pharmaceutical legislation, it is possible to challenge the legislation if it is contrary to constitutional provisions. In an American case of *U.S. v. Maryland Baking Company and Others*,¹¹⁶ a U.S. Court held an inspection to be illegal for which authority to enter had not been properly obtained. In this case, the Maryland Baking Company was reported for violating the Act. Agents of the Food and Drugs Agency did not make a request or eventually obtain manager's permission to inspect premises, but permission had been obtained from a subordinate

¹¹³ Pharmaceutical Act, 2004, s. 60(3) read together with s. 60(4), a warrant is supposed to be obtained before search and seizure.

¹¹⁴ Constitution of Zambia Act, Cap 1 Art. 17(1)

¹¹⁵ *Mulundika and 7 Others v. Attorney General* (1995- 1997) Z.R. 20

¹¹⁶ *U.S. v. Maryland Baking Company and Others* (D.C. Ga. 1948) 81F. Supp. 560

who was not authorised to grant such permission. For failure to comply with requirements of the Act, the inspection was held to be illegal, and evidence obtained and such inspection suppressed and declared inadmissible at trial. In this jurisdiction, a different view holds. In *Liswaniso v. The People*,¹¹⁷ the appellant challenged the admissibility of evidence obtained improperly as a result of an illegal search. it was held that any evidence obtained in an illegal search is admissible in evidence because it is a fact in the case. In this case, a police officer swore a false affidavit, which the Appellant's Counsel sought to impugn on grounds that it was not properly obtained. In addition, he sought the court's order that any evidence obtained by illegal means should have been and indeed should be inadmissible at the trial. The Court held against the Appellant, and refused to follow American jurisprudence and instead opted to be persuaded by English, Canadian and Indian cases law. In the opinion of the court, the public interest in prosecuting and preventing crime outweighed the individual interest of privacy even if that right is protected by the Constitution.¹¹⁸ This remains the precedent to this day, and all Courts in this jurisdiction are bound to follow it under the principle of *stare decisis*.¹¹⁹ This is a principle by which lower courts in the hierarchy of the Court system are bound to follow the decision of the higher court. Even the highest court can not lightly depart from its earlier decision, unless with excellent reasons.

However, notwithstanding the admissibility of the illegally obtained evidence, the infraction can be visited by civil or criminal sanctions. Therefore, the person who

¹¹⁷ *Liswaniso v. The People* (1976) Z.R. 277

¹¹⁸ Constitution of Zambia, Cap 1, Art 17(1). At the time of *Liswaniso* it was Art. 19

¹¹⁹ *Davies Jokie Kasote v. The People* (1977) Z.R. 75

conducted the illegal search can be prosecuted for the illegal search in criminal or tortuous proceedings in a Court of Law.¹²⁰

It is illegal to operate a pharmacy without it being registered.¹²¹ This to ensure that conditions exist for the safe and proper conduct of the business of pharmacy and that all standards of pharmacy practice are met. If any place is operating an unregistered pharmacy, it is shut down and the perpetrators prosecuted. The case of *The People v. Kaluba Kampamba*¹²² is an example. Kaluba was arrested in Ndola. He was accused of running an illegal Pharmacy in contravention of Section 14(1) and 14(2) of The Pharmaceutical Act 2004. He pleaded guilty in the Ndola Magistrates Court and was fined Nine Million Kwacha (K 9,000,000=00) or in default, imprisonment for seven months.

Inspectors also monitor what drugs are on the market, by visiting all places where these medicines are sold and checking to ensure that all drugs that all on the Zambian market are registered and a product licence obtained in accordance with the law.¹²³ If the medicines are not registered, they are seized and the perpetrators maybe prosecuted in a court of law. In *The People v. Lusaka Medi Camp and Others*¹²⁴ the defendants were accused of importing unregistered medicines contrary to section 40(1) of The Pharmaceutical Act, 2004 of The Laws of Zambia. They were convicted and fined and the Directors given a sentence of six months imprisonment suspended for two years.

¹²⁰ Supra, note 7

¹²¹ Pharmaceutical Act, 2004, s.14

¹²² *The People v. Kaluba Kampamba* (unreported) This is a Subordinate Course case concluded at the Ndola Magistrate's Court on 21st may 2008. Unfortunately, the cause number could not be traced. This information was obtained from the Pharmaceutical Regulatory Authority.

¹²³ Pharmaceutical Act, 2004, s.40

¹²⁴ *The People v. Lusaka Medi Camp and Others* (unreported). Another case without a cause number. Concluded at the Lusaka Magistrate's Court on 8th April 2008.

However, decisions of the Authority to seize certain substances that the Authority thinks break the regulations are open to challenge in the courts of law through judicial review. Judicial review has taken the place of the old prerogative writs of mandamus, certiorari and prohibition and those writs were issued because of the supervisory position of the High Court over inferior courts and over tribunals dealing with matters of public law.¹²⁵ The Pharmaceutical Regulatory Authority as a governmental body is amenable to judicial review proceedings. An action for judicial review may arise where a public authority exceeds its powers in the exercise of its powers. These powers may be held to be *ultra vires*, rendering the decision illegal. In *Derrick Chitala v. Attorney General*,¹²⁶ The appellant appealed against a decision of a Judge in the High Court who had summarily refused to grant leave to bring judicial review proceedings. The appellant had sought an order of certiorari to remove into the High Court for the purpose of quashing the decision by the President and his Cabinet to have the next Constitution enacted by the present National Assembly; an order of mandamus directed to and compelling the President and the Cabinet to take such measures as may be necessary to ensure that the Constitution was debated by and finally determined by a Constituent assembly and subjected to a referendum and ancillary relief. The appeal was dismissed, on the ground being that the president had not abused his powers, and therefore there was no issue of illegality. An action for judicial review may also arise where an incorrect procedure is used to arrive at a decision. In *Ridge v. Baldwin*,¹²⁷ Charles Ridge had been dismissed as Chief Constable of the County Borough of Brighton. He contended before the House of Lords that the

¹²⁵ Ludwig Sondashi v. Godfrey Miyanda (sued as General Secretary of the Movement for Multiparty Democracy) (1995 – 1997) Z.R. 1 at 2

¹²⁶ Derrick Chitala v. Attorney General (1995 – 1997) Z.R. 91

¹²⁷ Ridge v. Baldwin [1964] A.C. 40

principles of natural justice had been breached. The House of Lords allowed his appeal, holding that natural justice did apply and had not been observed. Judicial review may also lie where an act of the public body is anchored on an error of law. Another face of the rule of natural justice is the rule against bias. No man may be a judge in his own case. In *Zambia Airways Corporation v. Gershom Mubanga*¹²⁸ the Zambian Supreme Court held that the inclusion of two interested parties in the disciplinary committee that dismissed the respondent showed that the principles of natural justice were not followed. This was a case where the appellants had challenged the decision of the Judge in the High Court who had ordered the reinstatement of the respondent back into his job. Presence of two of the members of the appellant's management who sat on the disciplinary committee were interested parties and justice had not been seen to be done. Judicial review is also available where there has been an abuse of discretionary power on the part of the public authority, or where the power has been used for improper purposes. It may also arise where irrelevant considerations are taken in the process of making a decision. In this jurisdiction, there has been a challenge of the predecessor to the Pharmaceutical Regulatory Authority by way of judicial review. In *Sam Medical Products Limited v. Attorney General*¹²⁹ the Applicant took judicial proceedings against the Pharmacy and Poisons Board, the predecessor of the current Pharmaceutical Regulatory Authority. This was in respect of the seizure of Selenium, a nutritional supplement which was claimed to have curative properties against Human Immunodeficiency Virus (HIV). The applicant challenged the manner in which the Selenium was seized, alleging bad faith on the part of the Pharmacy and Poisons Board. The Court found that the Respondents acted properly

¹²⁸ *Zambia Airways Corporation v. Gershom Mubanga* (1990 -92) Z.R. 149.

¹²⁹ *Sam Medical Products v. Attorney General* (2004) HP/0802 (unreported)

and within its powers when it seized the product. This shows that all administrative decisions taken under this Act are open to challenge by way of judicial review. This includes retail, wholesale and import licencing decisions as well as decisions on what constitutes a poison or a medicine.¹³⁰

Before medicines can be manufactured in this country, a manufacturing licence must be obtained from the Pharmaceutical Regulatory Authority. No medicine can be legally manufactured in this country without a manufacturer's licence.¹³¹ This is to ensure that medicines are manufactured under safe and hygienic conditions. In *The People v. Juster Mukwala*¹³², the defendant was charged with one count of manufacture, import, export, distribution and sell of substandard, counterfeit, or adulterated medicines or allied substances contrary to section 33(1) of The Pharmaceutical Act, 2004 of The Laws of Zambia. He was accused of manufacturing *Tetrasil*, a drug preparation reputed to cure HIV and AIDS. Magistrate Sharon Newa found Mukwala guilty and sentenced him to five years imprisonment with hard labour.

This serves two purposes. First, it ensures that only medicines registered with the Authority in terms of section 37 and section 40 are allowed into the country. Those that are not registered are seized at the port of entry. To this effect, the Authority has inspectors at ports of entry to ensure compliance with this requirement. The second purpose is that, together with the requirement for product registration,¹³³ it ensures that medicines that are coming into this country are properly monitored, and that the

¹³⁰ Pharmaceutical Act, 2004, s. 55 for example. Relevant factors need to be considered before declaring a substance a poison. Arbitrariness is open to challenge.

¹³¹ Pharmaceutical Act, 2004, ss.20,21

¹³² *The People v. Juster Mukwala* SSP 146 of 2008(unreported)

¹³³ Pharmaceutical Act, 2004, s.37

Authority can be able to follow the chain of distribution from a foreign supplier, right up to the point where the medicine is supplied to the consumer. This minimizes the incident of counterfeit medicines being brought into the country.

Inspections are also carried out on any premises that are dealing in medicines or other substances that are subject of this Act, even if the premises are not registered with the Pharmaceutical Regulatory Authority. This is to ensure that medicines or other substances controlled by this Act are not sold on unauthorized premises. It makes no difference whether a registered pharmacist is employed or that medicines are sold under his supervision as long as the premises are not registered.¹³⁴

Another way of ensuring compliance is sensitisation. It works by disseminating information to members of the public. Although everybody is presumed to know the law, the facts on the ground are different. Most people do not know the salient provisions of the law. To increase acceptance of the law, it is important to move away from the draconian ways of command and control that was the preferred method in colonial times. Command and control systems are viewed as oppressive, and therefore unpopular. Instead of securing compliance through the threat of punishment, Sifuna and Mogere¹³⁵ suggest that policy may also be enforced through education, persuasion and incentives for compliance. Voluntary compliance is much more effective than that obtained by punishment. As explained in the previous chapters, health legislation is an issue of public security and therefore public interest. By explaining to the stakeholders how this piece of legislation is designed to protect their interests, it becomes easier to secure acceptance

¹³⁴ Pharmaceutical Act, 2004, s.16

¹³⁵ Sifuna N., and Mogere s., 'Enforcing Public Health Law.' Zambia Law Journal vol. 34 at 148

and, consequently, compliance with the provisions of this law. For example, by explaining to members of the public that they are actually putting their lives in danger by getting medicines from unregistered places and further explaining the reasons, that they cannot be sure of the safety of medicines because these unregistered places are not manned by qualified personnel, and that the source of medicines cannot be verified, members of the public will come on board and refuse to buy medicines from unregistered places. Medicines obtained from these unregistered premises are usually expensive, may be expired or even adulterated. In most cases, people are given the wrong medicines and often an incomplete dosage. When all this is explained, few people will buy medicines from unregistered places. Compliance, and as a consequence, achievement of the objectives of the pharmaceutical laws will be better achieved by members of the public feeling that they are doing something to protect themselves, rather than a perception that the government wants to deny them medicines.

Tip offs are usually given when a member of the public reports the presence of an unregistered pharmacy or illegal sale of medicines to the Pharmaceutical Regulatory Authority. These are usually members of the public who are enlightened and conscious of the dangers of medicines being sold from unregistered places. Other tip offs come from proprietors of registered pharmacies who spot unregistered pharmacies in their area of operation. Although the motive maybe to ensure that medicines that are supplied are safe, there is speculation that another motive may be the desire to eliminate the competition, who may be eating into their volume of business. Tip offs are also made by competing registered pharmaceutical concerns. For example, they may reveal that a competing

concern is selling counterfeit or fake drugs, or indeed one that is not registered, and has been smuggled into the country.

4.2 IMPLEMENTATION PROBLEMS¹³⁶

The Authority does not have sufficient human resource to ensure effective enforcement of the Act. A lot of positions in the approved human resource structures of the Pharmaceutical Regulatory Authority are still not filled. This poses several problems. First, the limited number of inspectors means that effective monitoring and inspections to ensure prescribed standards is not possible. As a result, inspections are focused on Lusaka and the Copperbelt province, with the rest of the country largely not monitored. Secondly, due to lack of manpower, the Authority is unable to deploy inspectors at ports of entry, except at Lusaka International Airport and Chirundu. The rest of the border ports of entry are not monitored. Thirdly, because of an insufficient compliment of staff, comprehensive regulations have not been developed to support full implementation of the Act. Development of these regulations requires technocrats who must be able to frame regulations that would be able to address and achieve what the Act requires. Fourth, the National Drug Quality Control Laboratory,¹³⁷ which is supposed to test the efficacy and composition, and hence safety of medicines, is also affected by lack of suitable human resources. An adequate complement of analysts and other scientists are required to ensure proper operation of the laboratory. As a result, most medicines find their way into this country without being tested, often relying on the claims of the importers of the drugs. This puts the safety of Zambians at risk, with medicines coming in likely to have only a

¹³⁶ Based on an interview with one of the Directors at Pharmaceutical Regulatory Authority conducted on 11th February, 2010.

¹³⁷ Set up by Pharmaceutical Act, 2004, s. 57

tiny fraction of the ingredient needed to treat a sick person. As an example, documented stories abound of Quinine preparations, a medicine used to treat malaria, that were found to contain insufficient amounts of Quinine to effect a cure.¹³⁸ Fifth, applications for registration of drugs must be analysed by qualified manpower, in this regard, qualified pharmacists. Shortage of manpower means that evaluation of new applications is not done as quickly as is necessary. This creates a backlog of applications and delays the introduction of the medicine on the Zambian market, which maybe a disadvantage to users hoping for new inventions of medicines to treat their ailments.

Yet another challenge identified is the lack of adequate and suitable transport to enable inspectors to roam the length and breadth of this country to do their monitoring and inspections. In areas that are difficult to access like rough terrain, it is necessary that all terrain vehicles are available. The Authority lacks this kind of transport. Therefore, certain parts of the country have never been visited.

¹³⁸ Patricia Barton, 'Quality of Quinine preparations in Indian Hospitals and Dispensaries.' Indian Medical Journal Volume 74, October 1939, as reported in the Article, "The Great Quinine Fraud," Social History of Alcohol and Drugs, University of Strathclyde, Glasgow. Volume 22 No. 1, 2007 at 6.

CHAPTER 5

SUCCESES AND FAILURES

The Pharmaceutical Act, 2004 has been in existence for almost six years now. Being a new Act, we must assess its successes and failures to understand its contribution to Zambian society.

5.1 SUCCESES

Enforcement of the Pharmaceutical Act, 2004 has met with mixed success. On the one hand, some evidence suggests that the fledgling Pharmaceutical Regulatory Authority's enforcement work has helped raise standards in the pharmaceutical field. It has also increased consumer protection, in that the safety of medicines is assured. For instance, chaotic drug imports have been curbed. While previously drugs used to be imported from all over, now every medicine must be registered and properly scrutinized before it can be allowed into the country.¹³⁹ Because of a comprehensive drug register, supplier audit is possible. The Authority is able to track drugs from manufacturer through retailer to consumer. That way, consumers are protected from counterfeit medicines. Points of presence are steadily increasing. Apart from the Lusaka International Airport and Chirundu, now there is another office in Ndola. Unlike previously when there were no active enforcement measures, there are now active prosecutions of offenders. Several convictions have been achieved as evidenced in the previous chapter.

¹³⁹ Pharmaceutical Act, 2004, s. 40(1). Only registered medicines can be imported into this country.

5.2 FAILURES – THE GAP

Perhaps the biggest failure or gap is the failure to facilitate legal sale of medicines in areas that are not serviced by registered pharmacists. The problem is best understood by considering observations of eminent persons on this matter. In the Legislative deliberations prior to the 1940 Act, Sir Leopold Moore, a member of the Legislative Council and the first pharmacist in this territory then Northern Rhodesia, who opened the very first pharmacy in this country in 1905 stated that it would be practically impossible to administer any poisons law in this country.¹⁴⁰ According to him, no poisons law could work in this country as nobody could operate it because there were no pharmacists to run pharmacies in the territory as envisaged by the bill. He estimated that there were only two pharmacists in the country at that time in 1940. It was therefore impracticable and unjust to restrict supply of certain medicines (poisons) since, if the law was strictly applied, only two pharmacies would operate in the whole territory. This means that other towns, let alone small settlements, would have no access to drugs. Any access would be illegal. Indeed, the resultant law was not strictly applied. Indeed, even after the enactment of the 1940 Act, with only a sprinkling of registered pharmacists in a few pharmacies, the rest were run and operated by non-pharmacists without any legal sanctions. This remained the status quo until the early 1990s. Colonel Stewart Gore-Brown, a representative for African interests observed that most of those medicines that the Act sought to control were used by people in serious need.

¹⁴⁰ Legislative Council debates No. 37. Fourth Session of the Sixth Council. 7th to 16th September, 1940. Col, 100

“we should not be committing an offence by giving medicine to our employees.”¹⁴¹

He further observed that by removing one injustice, namely introducing controls in order to safeguard the health of the people, we should be careful that we do not create another injustice by denying some people all access to life saving medicine. He gave an example of a person mauled by a lion at farm, in an area where the nearest hospital is hundreds of kilometers away and there is no reliable transport. Chances are that without the necessary medicine, the victim faces certain death, because it would be illegal for the farm manager to keep the necessary medicine. Another example is where a person is bitten by a venomous snake. For certain types of snakes, a victim can only survive for a maximum of thirty minutes before they succumb to the effects of the venom. Therefore, life saving anti venom must be administered within that window. It is practically impossible to rush a person to hospital, even in urban areas where it takes an ambulance over thirty minutes to reach a health centre. Even then, it takes another thirty minutes for a doctor to attend to a patient. That is one failure the Act has failed to address.

Industry players have been accused of favouring the status quo for various reasons. Indeed, there have been accusations that they sponsor certain sections of the law to favour them, at the expense of the general public. Economists have long recognized that regulation is not always enacted to improve efficiency and advance the public interest. It has often been argued that regulation is sought by specific industry groups in order to remove the competition, tilting the playing field to their advantage. For instance, by functioning as an entry barrier, regulation may raise the profits of incumbent firms by

¹⁴¹ Legislative Council debates No. 37. Fourth Session of the Sixth Council. 7th to 16th September, 1940. Col, 136

precluding the entry of new firms and new products. This is the situation obtaining here. Importers have complained that they cannot register some medicines on account of high registration fees.¹⁴² This means that a company that registers the drug has an effective monopoly on the drug. In the context of product quality regulations like those applying to food and drugs, regulation may help incumbent producers by making it more costly for newer products to enter the market. Indeed, regulations that require producers to meet certain minimum standards or that ban the use of certain additives may benefit incumbent producers at the expense of producers of cheaper substitutes. Such regulations may also harm consumers, whose needs may be better met by these new prohibited products. The observation that select producer interests are often among the most vocal proponents of regulation is consistent with this explanation for regulation.¹⁴³ Indeed, a desire to shift the competitive playing field in favor of the producers of certain products has historically been an important motivation for food and drug regulation.¹⁴⁴

Sale or supply of medicines or poisons in an unregistered pharmacy is clearly illegal. If the law is strictly enforced, all those selling medicines in towns that do not have a registered pharmacy would all be arrested and prosecuted. It is desirable that regulations are enforced to achieve the purpose for which they are intended, namely to protect the public, the vast majority of which are ignorant and those that do not stop to analyse when purchasing medicines or poisons.

¹⁴² Interview: Anonymous importer for fear of reprisals. November 23, 2009.

¹⁴³ Concerns led to removal of certain sections which would have criminalised sale of certain farming inputs. Farmers are a huge constituency. Farmers successfully fought off encroachment of control of Agricultural Chemicals by the Pharmaceutical Act, 2004. National Assembly debates 6th August, 2004, col. 881

¹⁴⁴ Stigler, George J. "The Theory of Economic Regulation." Bell Journal of Economics and Management Science 2, no. 1 (1971) at 3-21.

The answer may lie in looking at how certain jurisdictions have dealt with this problem. In the United States of America, certain States have applied the principle of necessity with varying results. They start by recognizing that it is not possible to attract pharmacists and doctors to be in every community mostly for economic reasons. The community may not be affluent enough to generate enough business to support a pharmacist or a doctor's practice. Secondly, the population may not be large enough to support the presence of a pharmacist or doctor. In certain districts, especially those that are sparsely populated, pharmacists cannot exist because there is not enough business to support them. Even doctors' clinics are non-existent. It therefore becomes necessary for the grocer to sell simple or ready prepared drugs.¹⁴⁵ Therefore, in the United States, certain States seized the initiative and legislated for just such eventualities. For example, a State of Wisconsin statute required different qualifications for pharmacists in towns of 500 or less.¹⁴⁶ This would mean allowing assistant Pharmacists, or Pharmacy Technologists in this jurisdiction, to operate and run such pharmacies. This provision was affirmed in *State v. Evans*¹⁴⁷ adding that the statute was not invalid because it did not provide the manner of determining the population. In another case, *State v. Donaldson*¹⁴⁸ in the State of Minnesota, shopkeepers who were more than one mile from a drugstore were allowed to sell common medicines and poisons under the rule of necessity. It was said to be reasonable in view of the necessities and convenience of those who resided at a distance from a drugstore. In yet another American case, it was held that sales of

¹⁴⁵ Arthur, W. *Drugs and Druggists*. West Publishing Company, Minnesota 1955 at 2

¹⁴⁶ Rev.St. 1898, s. 1409g

¹⁴⁷ *State v. Evans* (1907) 130 Wis. 381, 110 N.W. 241.

¹⁴⁸ *State v. Donaldson* (1889) 41 Minn. 74, 42 N.W. 781.

camphorated Oil and essence of peppermint were medicines and prohibited from sale except by registered pharmacists and assistant pharmacists or registered assistant pharmacists. However, the prohibition did not apply to rural districts.¹⁴⁹ In *People v. Roemer*,¹⁵⁰ in an action by the people of New York against John Roemer, section 234 of the Public Health Law allowed, in places of 1,000 inhabitants or less, storekeepers were allowed to sell certain drugs specified by the board. The section allowed sale of certain classes of medicines or poisons but only in original packages. The Court, in interpreting this provision, said that although the storekeeper is not authorised to compound medicines, he is also responsible for the quality and purity for all drugs sold by him subject to the guaranty of the drug.

“The question is whether for the sale of poisons and medicines which must necessarily mean prepared medicines (that is, such as do not require compounding by vendor), the state must compel dwellers in sparsely settled districts to resort to a pharmacy or drugstore, however distant, for articles that maybe needed for poisons or medicines. That would mean a farmer must go beyond his locality to purchase poisons used in his business, if a pharmacist has not settled within convenient reach, and that medicines sold in packages, however pressing the exigency, must under the same conditions be sought beyond the locality. That would be a denial of the convenient purchase of necessities and permit pharmacists, who shun scattering communities, to monopolise a trade at centers to which their traffic would not tend. Because a pharmacist must study and acquire knowledge to be such, it does not follow that some of his inferior powers may not be committed to less trained men who reside where persons of his class do not carry on business.”

In this jurisdiction, the 1921 law allowed sale of certain medicines by shopkeepers as long as they were in original packages.¹⁵¹ However, in later legislation, namely the 1940 Pharmacy and Poisons Act, this express provision was removed, in favour of a

¹⁴⁹ *Kratky v. Board of Pharmacy* (1929) 7 N.J. Misc. 970, 147 A. 726.

¹⁵⁰ *People v. Romer* (1915) 168 App. Div. 377, 153 N.Y.S. 323

¹⁵¹ Poisons Ordinance, Cap.98 of 1930, s.6(b)

discretionary power conferred on the Minister to exempt certain drugs and certain groups of people from strict regulations of the law.¹⁵² This is a recognition of the rule of necessity. However, this discretion has only ever been exercised to grant exemptions to certain mine hospitals,¹⁵³ leaving out other deserving areas and districts. In these areas, there was no enforcement, either because the body charged with enforcement lacked adequate manpower, or they chose to turn a blind eye as enforcing the law would have been unjust. Even in the current Pharmaceutical Act, 2004 exemptions are left to the minister.¹⁵⁴ However, the Minister has failed to exercise the discretion. It is submitted that the American approach is better because it confers a statutory right to sell medicines in certain areas under the rule of necessity, instead of relying on the Minister's discretion which he may never exercise. While the intention of having registered Pharmacist run pharmacies and dispensaries is good, the fact on the ground are that in most areas we don't have pharmacists,¹⁵⁵ for various reasons including not enough pharmacists to go round, and not enough business or population to support a pharmacy. As seen above, the Americans thought of a way to bridge the gap, by allowing sale of medicines in certain areas where Pharmacists were not available. Closer to home, Tanzania Medicines are dispensed in authorised outlets called Accredited Drug Dispensary Outlets (ADDO). These are outlets that do not employ pharmacists, but are authorised to sell essential prescription drugs.¹⁵⁶ These interventions have done a lot in terms of bridging the gap

¹⁵² Pharmacy and Poisons Act No. 38 of 1940, s. 18(c) which became s. 9 of Cap 299. This was the law in use up until 2004 when the Pharmaceutical Act, 2004 was enacted.

¹⁵³ Government notice No. 365 of 1964 granted exemptions to all mission hospitals and several mine hospital dispensaries.

¹⁵⁴ Pharmaceutical Act, 2004, s.31(c)

¹⁵⁵ View echoed by Honorable Mukwakwa when debating the Pharmaceutical Bill, 2004. National Assembly Debates 6th August, 2004. Col. 870

¹⁵⁶ Strategies for Enhancing Access to Medicines Project reports. www.msh.org/SEAM/5.2.htm accessed Nov 23, 2009.

between having access to essential medicines legally and having no access at all. Zambia can learn from this, and utilize the huge pool of qualified pharmacy technologists who are equivalent to American assistant pharmacists. These can adequately sell and supply medicines in areas where pharmacists are not available.

One other failure is that even after the Act being in existence for almost six years, there have been no regulations made under the Act to give effect to Statutory provisions. For example, under section 48(c), the Minister is empowered to make regulations specifying the herbal medicines which are subject of control. If no such regulations no exist, it means that despite the best intentions of the Act to control herbal medicines, they are technically not controlled.

CHAPTER 6

GENERAL CONCLUSIONS

The objective of Pharmaceutical laws is to protect the general public from counterfeit, bogus or adulterated drugs. It is one of the Police powers available to a state. Police power is one of the fundamental powers of any state. It is widespread and inclusive. In an American case of *Commonwealth v. Payne Medicine Company*,¹⁵⁷ it was stated:

“The police power of a state is far-reaching and in large measure undefined. Generally speaking, it may be invoked to control and regulate, or even prohibit the doing of anything that concerns the health, lives, morals, good order, and general welfare of the community.”

In Zambia, the law applicable as regards pharmaceuticals is the Pharmaceutical Act 2004. Regulation in Zambia benefitted by drawing on the experiences of those countries which were more experienced in drug regulatory issues. As a matter of fact, most of the provisions that found their way into Zambian pharmaceutical laws were copied from the British statute books.¹⁵⁸ The first ever law to try to regulate supply of medicines in Zambia was Proclamation No. 21 of 1921.¹⁵⁹ It was repealed by Act No. 38 of 1940, which was in turn repealed and replaced by the Pharmaceutical Act, 2004.

In practice, the Pharmaceutical Act, 2004 is enforced through inspections to ensure that the law is being observed. Imports are also monitored and regulations enforced to ensure

¹⁵⁷ *Commonwealth v. Payne Medicine Company* (1910) 138 Ky. 164, 127 S.W.760

¹⁵⁸ The Poisons Ordinance No. 21 of 1921 was largely a replica of the Pharmacy Act, 1908 of Great Britain. Ordinance No. 38 of 1940 of Northern Rhodesia was largely a reproduction of the Pharmacy and Poisons Act, 1933 of Great Britain.

¹⁵⁹ It became Ordinance No. 98 of the 1930 edition of Laws of Northern Rhodesia.

that only registered medicines as required by the law are allowed into the country. Breach of the law is sanctioned by seizures and prosecutions. In this vein, a number of convictions have been recorded.

However, strict application of this law has created problems of its own. While it is meant to ensure that safe and effective medicines reach the user through safe and reliable channels, that is through registered pharmacies, the facts on the ground show that strict observance of the law results in certain areas not being serviced by a registered pharmacy. The failure to facilitate legal sale of medicines in areas that are not serviced by registered pharmacists is a serious gap in the law. Sale or supply of medicines or poisons in an unregistered pharmacy is clearly illegal under the law as it stands today. This means that inhabitants of such areas are denied the right to access drugs within reasonable distance from their places of residence, which may spell death in situations where they need life saving emergency drugs like anti venom.

6.1 RECOMMENDATIONS

How can we remedy the situation? The answer lies in drawing on the experiences of other countries who have been in similar situations. The Americans have laws that allow certain stores that are not pharmacies to sell certain life saving drugs under the principle of necessity. Our friends across in Tanzania have what they call Accredited Drug Dispensary Outlets that are manned by staff other than pharmacists. In both these places, there has been tremendous relief. This has been achieved by the law recognizing certain

exceptions. The population that would be disadvantaged by strict application of an unmodified law requiring a pharmacist find service in these outlets.

We have seen that it is necessary to have a law that controls the supply of drugs. This ensures that safe, effective drugs are supplied to the public in order to safeguard their health. But it is also true that strict enforcement of the law would disadvantage a huge section of the community, because certain areas do not have pharmacies and pharmacists. One way of remedying the problem is for the minister to exercise his discretion and recognise that in certain areas where there are no pharmacists, provisions are made for other health professionals to run medicine stores. Another way is to amend the law expressly and allow for setting up of pharmacies under certain conditions in places where pharmacists are not available. Laws are supposed to serve the needs of society, and not society serving the law.

It is submitted that in Zambia, we should embrace the American or the Tanzanian approach. It has the advantage of a written law that can be applied by everyone, and not be left to the discretion of the minister.

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