

**AN EVALUATION OF THE EFFECTIVENESS OF THE LAW GOVERNING THE  
REGULATION OF PHARMACEUTICAL PRODUCTS AND ALLIED SUBSTANCES IN  
ZAMBIA**

**BY**

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**UNZA - 2011**

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REGULATION OF PHARMACEUTICAL PRODUCTS AND ALLIED  
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**BONAVENTURE CHILINDE**

**A DISSERTATION SUBMITTED TO THE SCHOOL OF LAW OF THE  
UNIVERSITY OF ZAMBIA IN PARTIAL FULFILMENT OF THE  
REQUIREMENTS OF THE AWARD OF THE DEGREE OF  
BACHELOR OF LAWS (LLB)**

**APRIL 2011**

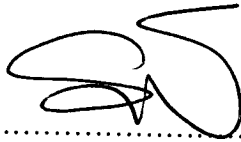
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## DECLARATION

I do, hereby solemnly declare that this work represents my own original work and that to the best of my knowledge no same or similar piece of work has been previously submitted for a degree at this or another University.

Signed: .....

A handwritten signature in black ink, consisting of stylized, overlapping loops and a final vertical stroke.

BONAVENTURE CHILINDE

April, 2011

## APPROVAL

I approve and recommend that this dissertation prepared under my supervision by BONAVENTURE CHILINDE entitled “An evaluation of the effectiveness of the law governing the regulation of pharmaceutical products and allied substances in Zambia” be accepted for examination as fulfilling the requirements or partial fulfilment of the requirements for the award of the Bachelor of Laws degree by the University of Zambia. I have checked it carefully and I am satisfied that it fulfils the requirements relating to the format as laid down in the regulations governing directed research.

Signed: .....

MABVUTO SAKALA (Supervisor)

APRIL, 2011

## **DEDICATION**

This work is dedicated to my wife Mwila, my children Besa and Ntazana for enduring my absence from home most of the times during the whole period of my studies.

## **ACKNOWLEDGEMENTS**

I wish to acknowledge and thank Mr. B. Kabika and Mr. O. Kamwale who are Inspectors at the Pharmaceutical Regulatory Authority for their immense contributions on various cases relating to the Pharmaceutical Act, No. 14 of 2004 referred to in this research.

I also wish to recognise the efforts of my supervisor Mr. Mabvuto Sakala for his dedicated guidance, support and encouragement from the onset of this research to the end.

Lastly, my gratitude extends to Siwela Malunga and Richard Lubinda for the encouragement to move on even when studies got tough.

## ABSTRACT

The Pharmaceutical industry in general requires a well outlined laws to ensure proper control. The Zambian pharmaceutical industry is not an exception to this. The law governing the industry in Zambia is the Pharmaceutical Act No.14 of 2004 which repealed the 'Pharmacy and Poisons Act, 1940' and the 'Therapeutic Substances Act, 1968'. The previous laws were administered by the defunct 'Pharmacy and Poisons Board' which was a department in the Ministry of Health. The 'Pharmacy and Poisons Board' did not have much powers to prosecute cases that came before it as regards medicines because the law applied then did not provide for necessary sanctions. The 'Pharmacy and Poisons Board' largely depended on the Zambia Police to prosecute cases that came up.

The enactment of the Pharmaceutical Act No.14 of 2004 established the Pharmaceutical Regulatory Authority which took over from the activities of the 'Pharmacy and Poisons Board'. This is a body corporate that can sue and be sued. Since its inception, a number of cases have been prosecuted against those that have been operating against the law. The current law governing the pharmaceutical industry has made a positive impact in bringing sanity to the industry.

The court cases that have been handled by the Pharmaceutical Regulatory Authority have had a derrent effect to would be offenders in the industry.

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## CHAPTER ONE

### 1.0 Introduction

The pharmaceutical industry is a specialised industry dealing in products to do with human and animal health. As such, there is a serious need of close regulation to ensure that all stake holders abide by well-defined laws in carrying out their business.

Pharmaceutical and allied products come in different forms and for various purposes. Some products are made freely available to consumers while others are more strictly controlled and are only dispensed by trained personnel to handle such materials. Across the counter medicines found in open super markets include such drugs as Paracetamol tablets, Aspirin tablets and cough remedies. These are called general sales drugs abbreviated by G. The strictly controlled products are only sold by a prescription from a registered pharmacy and are called prescription only medicines abbreviated P or POM. In Zambia, dispensing of medicinal products and allied substances is by law a preserve of individuals trained in pharmacy. The training of such pharmacy personnel is at technician level and full pharmacist level<sup>1</sup> unless otherwise allowed for special reasons. Pharmacy technicians are only allowed to handle certain prescribed products while pharmacists are licensed to handle the full range of available medicines within the provisions of the law<sup>2</sup>.

Pharmaceutical wholesale and retail outlets also play a major role in the industry. Normally patients would access medicines either at a hospital pharmacy or a retail outlet commonly known as chemists. These retail outlets would in turn procure their merchandise from pharmaceutical wholesale companies. These wholesale companies in turn source their products from pharmaceutical manufacturing companies. Regulation of the manufacturing

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<sup>1</sup> Sections 6(1), 8(2)(i) and (j), The Health Professionals Act, 2009

<sup>2</sup> Section 12, Pharmaceutical Act, No. 14 of 2004

industry is more stringent as compared to the wholesale and retail pharmacy. Each manufacturer is licensed to produce a specified list of products. The manufacturing facility must meet minimum requirements<sup>3</sup> for the manufacture of medicines. Medical and surgical equipment also play an important role in the healthcare delivery system. These include syringes, solution giving sets, surgical materials and other specialised medical equipment. All these have to be regulated to ensure only the correct and approved supplies are used on patients.

Importation and exportation of medicines is also controlled based on World Health Organisation regulations. This is to ensure supply of safe and efficacious medicines to the world population. In Zambia, traditional medicines also play a key role in the day to day life of the people. The activity of the traditional-medicines practitioners also requires a level of regulation.

This chapter gives a general overview of the pharmaceutical industry and the law governing activities there in.

## **1.1 Law**

The Law governing the regulation and use of pharmaceutical and allied products in Zambia is the 'Pharmaceutical Act No.14 of 2004' here in referred to as the 'Pharmaceutical Act'. The institution tasked with the responsibility to ensure that stake holders in this industry operate within the law is the 'Pharmaceutical Regulatory Authority' which in this research is also referred to as the 'Authority'. The institution is the creation of the Pharmaceutical Act No.14 of 2004. Through this law, the 'Pharmaceutical Regulatory Authority' is empowered to offer advice, approve and licence all outlets dealing in medicines in Zambia.

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<sup>3</sup> Factories Act, Cap 441 of 1966; Local government Act, Cap 281 No.6 of 2010

The 'Authority' also ensures that only safe and potent medicines are made available to the people. The institution is at high alert for any products on the market that would bring negative effects on the members of the public. Any counterfeit medicines and medical supplies found on the market are confiscated and destroyed by the 'Authority' in line with public health policy.

## **1.2 Statement of the Problem**

After the 1991 revolution back into a multiparty democracy, there has been a steady increase in economic investment in Zambia. With the increase in economic players, there is always need to review practice procedures and laws required in regulating each economic sector. The pharmaceutical sector is not an exception to this. During the second republic, there were few viable pharmaceutical retail and wholesale outlets. The manufacturing industry was also not well explored. After the Movement for Multiparty Democracy (MMD) came into power in 1991, there was an appreciable growth in this sector. As several economic policies were being encouraged for the growth of the private enterprise as opposed to a government controlled mono economy, a number of business entrepreneurs entered into this arena. In Lusaka, notable ones included stable retail outlets like Link pharmacy, Jubilee Chemists and Cairo Chemists.

The industry also had new entrants in the manufacturing sector. In Lusaka, companies such as Pharco Limited, Pharmanova (Z) Limited, Kings Pharmaceuticals Limited and Tejay Pharmaceuticals Limited came on to contribute to the growth of the pharmaceutical activities. The industry also saw the resumption of manufacturing activities at International Drug Company. On the other hand, the industry experienced an increase in the number of

imports of various medicines in the generic and patented lines. Medical devices such as male and female condoms have also found root in our local market.

As indicated earlier, with such growth there was need to revisit the laws that were governing the control and use of pharmaceutical substances to safe guard the public from unsafe and less efficacious products. This led to the enactment of the Pharmaceutical Act, No. 14 of 2004 which repealed the 'Pharmacy and Poisons Act, 1940' and the 'Therapeutic Substances Act, 1968'.

The need to review the law then was to strengthen the regulation of all stake holders in the industry. As noted by R. Kampamba; a former Principal Pharmacist in the Ministry of Health and the defunct 'Pharmacy and Poisons Board'; who is also widely accredited in putting together the current pharmaceutical regulations, he stated that the 'Pharmaceutical Act' was a progressive piece of legislation though there were still challenges as far as enforcement of the new law was concerned<sup>4</sup>.

It is now seven years since the enactment of the 'Pharmaceutical Act'. The question is whether the 'Pharmaceutical Act' has fulfilled the drafters' expectations. As any industry develops, regulated stake holders tend to find ways and means of eluding the authority as they maximise their profits. The pharmaceutical industry is not an exception and that is why an effective legal control tool was required. The 'Pharmaceutical Society of Zambia' has emphasised from time to time that an effective regulatory authority ensures that there is sanity in the pharmaceutical industry<sup>5</sup>.

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<sup>4</sup> S. Mulenga, Enforcement Challenges of Pharmaceutical Legislation in Zambia (UNZA April 2010), p 6

<sup>5</sup> [http://www.postzambia.com/post-read\\_article.php?articleId=8487&highlight=Pharmaceutical%20Society](http://www.postzambia.com/post-read_article.php?articleId=8487&highlight=Pharmaceutical%20Society).  
Date Accessed: 15/09/2010

This study therefore intended to investigate the effectiveness of the ‘Pharmaceutical Act’ as applied by the ‘Pharmaceutical Regulatory Authority’ in regulating this dynamic industry to ensure public safety as regards pharmaceutical products and allied substances.

### 1.3 Purpose of the Study

The purpose of the study was to explore the various cardinal and operational provisions of the ‘Pharmaceutical Act No. 14 of 2004’ and evaluate their effectiveness as intended by its drafters. The research endeavoured to bring out various cases handled by the “Pharmaceutical Regulatory Authority” since its inception as it applied the law and reviewed how effective the enforcement has been as compared to the way the repealed laws were applied. The study also focused on how issues of illegal drug stores<sup>6</sup> had been handled based on the new law. This issue of regulating the pharmaceutical industry is of general concern among stakeholders and the public at large. There are a lot of illegal and unregistered medicinal products on the market especially in common township markets. These products pose a danger to the general public. Some of the medicines on the market are even in languages like *Swahili* and *Chines* which are not common languages in Zambia.

The president of the ‘Pharmaceutical Society of Zambia’, Mr. Bonaventure Kasama in reference to illegal drug outlets once indicated that:

“.... Zambians will not have access to quality medicines until a time when illegal drug stores were abated”<sup>7</sup>.

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<sup>6</sup> The People v Kaluba Kampamba. SSP at Ndola, 21<sup>st</sup> May 2008 (unreported)

<sup>7</sup> [http://www.postzambia.com/post-read\\_article.php?articleId=10548&highlight=Pharmaceutical%20Society](http://www.postzambia.com/post-read_article.php?articleId=10548&highlight=Pharmaceutical%20Society).  
Date Accessed: 15/09/2010

The study also explores how “the Pharmaceutical Regulatory Authority” has handled matters of illegal production of pharmaceutical products<sup>8</sup>, counterfeits, substandard products<sup>9</sup>, expired products<sup>10</sup> and labelling requirements. All this is necessary in safe guarding public health. For example, lack of stringent regulatory procedures caused the fateful calamity in United States of America where people died in the Elixir Sulfanilamide tragedy in 1937 which prompted Congress to pass the Food, Drug, and Cosmetic Act in 1938<sup>11</sup>.

This study endeavoured also to find out the extent of awareness of the Pharmaceutical Act No. 14 of 2004 by the partners in the pharmaceutical Industry and the public in general. From the manufacturing sector’s view, the study will seek to review how the “Pharmaceutical Regulatory Authority” has been handling cases regarding clinical trials and new chemical entities on the market.

#### **1.4 Significance of the study**

The current Pharmaceutical Act No.14 of 2004 was enacted because of the realised need to set the law regulating the industry to match the current trends. The industry required a more modern focussed law with penalties sufficient enough to deter those that want to abuse regulations in the industry<sup>12</sup>. So, it was necessary to review how effective the relevant legal provisions regulating the sector have been fairing as compared to the repealed laws. Good laws and regulations in the pharmaceutical industry which directly impacts on the health of the nation are cardinal especially in this era of deadly diseases like

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<sup>8</sup> Sam Medical Products v Attorney General (2004) HP / 0802 (unreported)

<sup>9</sup> <http://www.pharmaceutical-int.com/news/pharmaceutical-regulatory-authority-checks-zambian-viracept-supply.html>. Date Accessed: 15/09/2010

<sup>10</sup> Pharmaceutical Act, 2004, s 34

<sup>11</sup> <http://www.drugstudy.md/resource9.html>. Date accessed: 15/09/2010; s 35

<sup>12</sup> The People v Lusaka Medi Camp and Others. SSP at Lusaka, 8<sup>th</sup> April 2008 (unreported)

tuberculosis and infections relating to the high immune deficiency syndrome (HIV). For society to fight the problems associated with these health challenges, a supply of efficacious and potent medicines is required. This can only be realised when necessary adequate laws governing the supply chain and quality assurance of medicines are in place to ensure that sufficient ground is covered for the purpose of regulation to achieve progressive and positive results.

Some of the objectives of the study were:

- i. to investigate how the Pharmaceutical Regulatory Authority has applied the Pharmaceutical Act No. 14 of 2004.
- ii. to examine the role which the Pharmaceutical Regulatory Authority plays as an institution in exercising its power as provided in the Pharmaceutical Act No. 14 of 2004.
- iii. to look at some of the cases handled by the 'Pharmaceutical Regulatory Authority' based on the Pharmaceutical Act No.14 of 2004.
- iv. to make recommendations to strengthen the law required in areas noted to be weak as regards regulation.

## **1.5 Methodology**

The research study took a qualitative approach to evaluate the effectiveness of the law governing the pharmaceutical industry in Zambia. Review of documents from previous works in the field was done to link them to the current study. Case law was referred to in the research though most of the cases are unreported. Interviews were carried with persons that have directly been involved in the formulation of the current law or have been at the centre of implementation of the Pharmaceutical Act No. 14 of 2004. The research was

conducted within a sample pooled from the experts and partners in the Pharmaceutical sector<sup>13</sup>.

## **1.6 Organisation of the Study**

This research study is organised in 5 Chapters. Chapter 1 gives a general view of the subject under review as an introduction of the study. It highlights the industry's atmosphere and the need to regulate it as regards operations by different players there in. It also makes reference to repealed laws which have been replaced by the Pharmaceutical Act No.14 of 2004. Chapter 2 endeavours to bring out salient provisions of the Pharmaceutical Act No.14 of 2004 which in general have made a difference from the repealed laws.

Chapter 3 looks in detail at the review of enforceable substantive sections of the Pharmaceutical Act No.14 of 2004 and relating to provisions related to cases that have arisen since its enactment as intended by of legislators. Chapter 4 relates the Pharmaceutical Act No.14 of 2004 to the industry in general. The researcher's interest was to evaluate the extent to which the new law had reached in influencing how business was conducted by the partners in the industry. The last chapter forms the general conclusion of the research and recommendations. Comparisons will be made between the provisions of the current law to those of the repealed two Acts where enforcement and penalties are concerned.

## **1.7 Ethical Considerations**

In conducting the research, a high level of confidentiality was observed regarding the information the researcher came across in relation to the sources. All responses to questions in questionnaires or interviews remain the preserve of the researcher and no

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<sup>13</sup> M. Peil, P.K. Mitchell and D. Rimmer, *Social Research Methods An African HandBook*. (Bangalore: Macmillan India, 1985) p26

individual is mentioned in here as to any response but only with their informed consent<sup>14</sup>.

In the next chapter we will start by evaluating some of the provisions of the Pharmaceutical Act No.14 of 2004. Comparisons will also be made to some of the provisions which were under the previous laws governing regulation of the pharmaceutical Industry.

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<sup>14</sup> C. and D. Nachmias, *Research Methods in the Social Sciences*. (London: Anorld, 1990) p 323

## CHAPTER TWO

### 2.0 The Pharmaceutical Act No. 14 of 2004

The pharmaceutical Act No.14 of 2004, here in referred to as the ‘Pharmaceutical Act’ repealed the Pharmacy and Poisons Act, 1940 and the Therapeutic Substances Act, 1968 which used to guide the defunct Pharmacy and Poisons Board in the regulation of pharmaceutical products and allied substances in Zambia. The ‘Pharmaceutical Act’ established the Pharmaceutical Regulatory Authority<sup>15</sup> here in referred to as the ‘Authority’.

The major functions of the ‘Authority’ are to provide for the registration and regulation of pharmacies and medicines intended for human and animal use. The mandate extends to the registration, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances. The pharmaceutical manufacturing sector is also governed and regulated by the Pharmaceutical Regulatory Authority.

The ‘Pharmaceutical Act’ is arranged in eleven parts with two schedules.

Part I provides for references regarding the required interpretations. Part II provides for the establishment and functions of the Pharmaceutical Regulatory Authority. Part II prescribes requisites for registration of pharmacies. This part also spells out the required standard practices in the pharmaceutical industry.

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<sup>15</sup> Section 4 (1) of the Pharmaceutical Act

Part IV deals with license requirements to conduct business in the pharmaceutical industry. Part V of the 'Pharmaceutical Act' refers to requirements for registration of medicines, herbal medicines and allied substances in Zambia.

Part VI explores further the requirements for importation, exportation and use of various herbal medicines. Requirements to carry out clinical trials for medicines are provided for under part VII of the 'Pharmaceutical Act', and Part VIII refers to measures regarding the control of poisons.

One of the major inclusions in the Pharmaceutical Act No.14 of 2004 under Part IX, which was not provided for in repealed 'Pharmacy and Poisons Act, 1940' and the 'Therapeutic Substances Act, 1968' is the establishment of the national drug quality control laboratory under the control of the Pharmaceutical Regulatory Authority.

Provisions regarding the appointment of inspectors and other relevant officers of the 'Authority' are provided for under Part X. Lastly Part XI deals with general provisions.

## **2.1 The Pharmaceutical Regulatory Authority**

The Pharmaceutical Act No.14 of 2004 establishes the Pharmaceutical Regulatory Authority<sup>16</sup> here in referred to as the 'Authority'. It states that:

‘...here is hereby established the Pharmaceutical Regulatory Authority which shall be a body corporate with perpetual succession and a common seal, capable of suing and of being

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<sup>16</sup> Section 2(b), Pharmaceutical Act, 2004

sued in its corporate name, and with power, subject to the provisions of this Act, to do all such acts and things as a body corporate may by law do or perform’.

Among various functions under the mandate of the Pharmaceutical Regulatory Authority is to register medicines, herbal medicines and licence allied substances<sup>17</sup>. This means then that, dealing in the sale and purchase of medicines for resale without prior authority is an offence under the law. The Pharmaceutical Regulatory Authority registers pharmacies and licence any premises earmarked to be used for purposes of manufacturing, importing exporting, distribution and sale of medicines<sup>18</sup>. In the same vain, manufacturers of pharmaceutical products are also regulated and controlled by the ‘Authority’ to serve and protect public interest<sup>19</sup>.

All clinical trials on human beings or animals to be conducted in Zambia is regulated and monitored by the ‘Authority’. Post market surveillance is another mandate conferred on the institution to monitor adverse drug reactions.

The national drug quality control laboratory to be established shall fall under its control. This laboratory shall establish, maintain and enforce standards for privately owned drug control laboratories.

The Pharmaceutical Regulatory Authority is headed by the Director General who is the chief executive officer appointed by the board with approval from the minister. The Director General is responsible for the day to day administration of the ‘Authority’ subject to control of the board<sup>20</sup>.

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<sup>17</sup> Section 5(1)(a), Pharmaceutical Act, 2004

<sup>18</sup> Section 5(1)(b), Pharmaceutical Act, 2004

<sup>19</sup> Sections 5(c) and 5(f), pharmaceutical Act, 2004

<sup>20</sup> Section 11(1), Pharmaceutical Act

### **2.1.1 Powers of the Pharmaceutical Regulatory Authority**

The 'Pharmaceutical Act' provides for the powers and authority of the Pharmaceutical Regulatory Authority. Under section 6(1) (a), it provides that:

'... the Authority shall have power to direct any pharmacy or person providing services relating to the manufacture, importation, exportation, distribution and sale of medicines, herbal medicines and allied substance to deliver its services in such manner as to ensure compliance with this Act..'

This means then that the law requires that any pharmacy, manufacturer, wholesale dealer, distributor, importer, exporter or person to submit such information and records as may be necessary to enable the Pharmaceutical Regulatory Authority by notice served on the person or in the gazette, direct such person or persons to return any medicine, herbal medicine or allied substance to the manufacturer, importer or deliver it to the 'Authority' which that company or person has in their possession if in its opinion it is not in public interest<sup>21</sup>.

The 'Authority' may, by notice in writing, further direct in section 7(2) to 7(4) that:

(2) The Authority may, by notice in writing, direct any manufacturer or importer of the medicine, herbal medicine or allied substance referred to in subsection (1) or the person referred to in paragraph (c) of subsection (1) who has in their possession any quantity of such medicine, herbal medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) A person shall not sell any medicine, herbal medicine, or allied substance which is the subject of a notice under subsection (1).

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<sup>21</sup> Section 7, Pharmaceutical Act

(4) Any person who contravenes subsection (3) commits an offence and is liable, upon conviction to a fine of not less than fifty thousand penalty units but not exceeding one hundred thousand penalty units or to imprisonment for a term of not less than six months but not exceeding five years, or to both.

## **2.2 Registration of Pharmacies**

The 'Pharmaceutical Act' prescribes who should be allowed to handle medicines, herbal medicines and allied substances. Section 12 states that:

- (1) Subject to the other provisions of this Part a person who is not a registered pharmacist shall not-
    - (a) carry on, either on that person's own behalf or on behalf of another person the business of a pharmacist;
    - (b) in the course of any trade or business-
      - (i) procure, supply package, label, prepare, admix, compound, sell or dispense any medicine or allied substance or supply any poison; or
      - (ii) assure quality of medicines in practice;
  - except under the immediate supervision of a registered pharmacist
  - (c) assume, take, exhibit or in any way make use of any title, emblem, description or addition reasonably calculated to suggest that, that the person is registered as a pharmacist.
- (2) For the purpose of paragraph (c) of subsection (1), the use of the word "pharmacist" or "chemist" or "druggist" or any similar word or combination of words shall be considered to be reasonably calculated to suggest that the person having control of the business on those premises is a registered pharmacist.

To operate a pharmacy, an interested individual or company must obtain a licence from the 'Authority'. The 'Pharmaceutical Act' provides in section 13 that:

- (1) A person who wishes to operate a pharmacy shall, at least sixty days prior to the date the person intends to operate such pharmacy make an application for a pharmacy registration certificate in the prescribed form to the Director-General and provide evidence satisfactory to the Authority-
  - (a) a regarding the ownership of the pharmacy;
  - (b) regarding the suitability of the premises for use as a pharmacy; and
  - (c) that a registered pharmacist will manage and control the pharmacy at all times that the practice of pharmacy is being engaged in.
- (2) Where the applicant is not a registered pharmacist the application shall state the name of the registered pharmacist who is designated by the applicant as the manager of the pharmacy.
- (3) Where the applicant is a corporation, the application shall state-
  - (a) the name of the registered pharmacist who is designated by the applicant as the manager of the pharmacy;
  - (b) the name of every director of the corporation who is a registered pharmacist if any; and
  - (c) the names and addresses of the directors of the corporation.
- (4) The Authority shall, within sixty days of receipt of an application under subsection (1), issue a registration certificate, subject to such terms and conditions as the Authority may specify if the applicant and the pharmacy and its proposed operation satisfy the requirement of this Act.

(5) A registration certificate issued under this section shall be valid for such period as may be specified in the registration certificate and shall be renewable for a like period if the applicant has been complying with the provisions of this Act and upon payment of a prescribed fee.

(6) Where the Authority is not satisfied with an application to issue a pharmacy registration certificate the Authority shall within sixty days of receiving the application, refuse to issue the registration certificate to the applicant and shall state the reason for the refusal.

(7) Every person carrying on the business of a pharmacist shall cause each set of premises where such business is carried on to be registered in accordance with this section.

(8) The Authority shall keep a register of pharmacies registered under subsection (1).

From this section, one would see that the law prohibits any person to carry out the business of operating a pharmacy except with a valid pharmacy registration certificate.

Any person contravening section 13 commits an offence and is liable upon conviction to a fine or imprisonment or both.

Section 14 (2) provides that:

‘.. any person who contravenes subsection (3) commits an offence and is liable, upon conviction to a fine of not less than fifty thousand penalty units but not exceeding two hundred thousand penalty units or to imprisonment for a term of not less than six months but not exceeding five years, or to both.’

It is an offence under the law to operate any business dealing in the stocking of medicines without the necessary licences issued by the Pharmaceutical Regulatory Authority<sup>22</sup>.

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<sup>22</sup> The People v Trywell Zebron Tembo, SSP at Lusaka, 8<sup>th</sup> December 2008, (unreported)

## 2.3 Licences

As indicated in 2.1.1 above, the 'Pharmaceutical Act' requires that every manufacturer, wholesaler, importer or distributor shall not manufacture, act as a wholesale dealer of, import or distribute, as the case may be, any medicines or allied substances unless that manufacturer, wholesale dealer, importer or distributor is a holder of a license<sup>23</sup>.

In this light, the Pharmaceutical Regulatory Authority has its offices in Lusaka and Ndola to carry out the necessary inspections for would be offenders. The defunct 'Pharmacy and Poisons Board' only had an office in Lusaka.

The 'Authority' has ensured the presence of its inspectors on major border points in Zambia. In the southern part of Zambia, there are inspectors at Chirundu, Livingstone and Kazungula border posts to ensure that only registered medicines and allied substances enter the country. Lusaka international entry point is one such major inspection point as most medicines of high value enter the country through air transport<sup>24</sup>. Currently, the Nakonde border post in the northern province of Zambia and the Kasumbalesa border post with the Democratic Republic of Congo on the copperbelt province have no stationed inspectors due to lack of man power.

The 'Authority' may require any person who imports medicines or allied substances for personal use to obtain clearance at the port of entry. Manufacturing companies wishing to manufacture pharmaceutical products and allied substances must apply to the Director General of the 'Authority' in a prescribed form and upon payment of such prescribed fees. The 'Authority' may issue to such a manufacturer a licence to manufacture medicine or

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<sup>23</sup> Section 20 (1), Pharmaceutical Act

<sup>24</sup> MSH: Quality Assurance of Medicines in Zambia - An Assessment Visit to the Zambia Pharmaceutical Regulatory Authority: Trip Report, p14

allied substances upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing practices<sup>25</sup>. Wholesale dealers are also required to comply with such respective requirement to operate their premises.

The ‘Authority’ may suspend or revoke any licence issued under the ‘Pharmaceutical Act’ if it is satisfied that the licensee has failed to comply with any of the conditions relating to the licence. The notice for such revocation or suspension shall state the reasons for the intended action<sup>26</sup>.

The minister may on recommendations of the ‘Authority’ and by statutory instrument make regulations when necessary. Regulations include conditions attached to each licence and fees payable for various purposes<sup>27</sup>.

In special cases such as where there is a dire need of certain medicaments rarely available on the market and in small quantities for personal use, the ‘Pharmaceutical Act’ provides for exceptions at the discretion of the Director General.

Other exemptions in the ‘Pharmaceutical Act’ relating to requirements of licensing and registration in relation to possession of medicines and allied substances are applicable to supplies by a duly qualified and registered medical practitioner, dentist, veterinary surgeon, registered nurse and registered midwife in the ordinary course of practice for that medical practitioner, dentist, veterinary surgeon, registered nurse or registered midwife<sup>28</sup>.

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<sup>25</sup> Section 21 (1), Pharmaceutical Act

<sup>26</sup> Section 26 (1), 26 (4), Pharmaceutical Act

<sup>27</sup> Section 29, Pharmaceutical Act

<sup>28</sup> Section 31, Pharmaceutical Act

Government employees in special cases with the permission by the minister in consultation with the 'Authority' and especially in rural areas may be exempted from the requirement of licensing to handle and supply medicines where qualified personnel are not available. This exemption also applies to hospital dispensaries.

## **2.4 Offences and penalties**

The 'Pharmaceutical Act' provides for offences and penalties regarding licences.

Section 32 of the 'Pharmaceutical Act' states that:

(1) Any person who fraudulently obtains a licence under this part commits an offence and shall be liable, upon conviction, to a fine not exceeding one hundred thousand penalty units or to imprisonment to a term not exceeding seven years, or to both.

(2) Any person who-

(a) deals in unregistered medicines or allied substances;

(b) fails to maintain records for medicines or allied substances registered under this Act; or

(c) obtains medicines or allied substances from unauthorized suppliers;

commits an offence and shall be liable, upon conviction, to a fine not exceeding three hundred thousand penalty units or to imprisonment to a term not exceeding ten years, or to both.

(3) In addition to the penalty provided in subsection (1) and (2) the court before which a person is convicted of an offence under this section may order that any medicines or allied substances in respect of which the offence is committed be forfeited to the State.

Offences also refer to any person who manufactures, imports, exports, distribute or sell substandard, counterfeit or adulterated medicines or allied substances that they shall be liable upon conviction to prescribed penalty units or imprisonment or to both<sup>29</sup>.

The rampant sell of cosmetics on the market and especially skin lightening creams is prohibited under the 'Pharmaceutical Act'. Any person who contravenes section 62 (1) commits an offence and shall be liable on conviction, to a fine not exceeding fifty thousand penalty units or to imprisonment to a term of not less than eighteen months but not exceeding five years or both.

This is one area of enforcement that has posed a challenge to the 'Authority'. Efforts have been made in the past to confiscate some of these harmful cosmetics especially those which are Quinoline and Mercury based, but these illegal suppliers have outpaced the rate at which the 'Authority' confiscates them with quick resupplies and especially that a sizeable number of Zambian women use them one way or the other<sup>30</sup>.

When dealing with corporations, and where an offence under the 'Pharmaceutical Act' is committed by a corporation, every director or senior officer of that corporation shall be liable upon conviction, as if such director or senior officer had been personally guilty of the offence unless such director or senior officer proves to the satisfaction of the court that the act constituting the offence was done without his consent or knowledge<sup>31</sup>.

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<sup>29</sup> Section 33, Pharmaceutical Act

<sup>30</sup> Interview : Mrs. C. Yeta, 2/02/2011

<sup>31</sup> Section 63, Pharmaceutical Act

## **2.5 The national drug quality control laboratory**

The establishment of the laboratory to evaluate the efficacy and safety of medicines and allied substances has been applauded as one of the progressive provisions in the 'Pharmaceutical Act' in relation to the repealed laws governing the regulation of medicines.

Section 57 provides that:

There is hereby established the National Drug Quality Control Laboratory which shall be managed by the Authority and which shall facilitate the regulation of medicines and allied substances under this Act.

Section 58 outlines the main purposes of the laboratory in the regulation of medicines and allied substances that:

- (1) The Authority shall use the Laboratory-
  - (a) to verify the safety, quality and efficacy of medicines, herbal medicine, allied substances and poisons which are manufactured or imported into the country by persons who are licensed under this Act;
  - (b) to analyse and conduct research on herbal medicines, allied substances and poisons;
  - (c) to provide laboratory services to the general public;
  - (d) to provide practical training for personnel in the analysis of medicines, herbal medicines, and allied substances;

(e) to perform such other functions relating to the analysis of medicines, herbal medicines, allied substances or poisons as it considers necessary.

(2) The Authority shall charge such fees for any analysis of medicines or services provided by the Laboratory as the Authority may determine.

(3) The Authority shall appoint a Director for the Laboratory who shall be responsible for the day to day administration of the Laboratory.

(4) The Authority shall appoint such number of pharmaceutical analysts as it may consider necessary for purposes of performing its functions under this section.

The national quality control laboratory has already started installing equipment with the help of funding from the European Union. This indeed will strengthen the capacity in the 'Authority' in the chemical and biological analysis medicinal and allied products. Previously, the 'Authority' used to face challenges because of using laboratories of market players. In case of litigation, it used to be difficult for the court to regard such results as being fair as they were conducted by market competitors. The other aspect being considered by the 'Authority' is the legal department to concentrate on prosecuting cases that are brought to the attention of the 'institution'.

Generally, the Pharmaceutical Act, No14 of 2004 has been held as a more relevant legal instrument compared to the repealed laws governing medicines and allied substances in Zambia. Its systematic drafting and relevant contributions by experienced professionals in the pharmaceutical field in Zambia towards its enactment has made it more relevant than the previous borrowed laws, the Pharmacy and Poisons Act of 1940 and the therapeutic Substances Act of 1968 adopted from the British laws at independence.

## CHAPTER THREE

### 3.1 Enforcement of the pharmaceutical Act No.14, 2004

Under the defunct 'Pharmacy and Poison Board' which has been replaced with the 'Pharmaceutical Regulatory Authority', there wasn't much litigation recorded. In most cases the regulating body just used to issue sanctions of either closing the premises or confiscating such items involved in any illegality. Most of the cases regarding medicines especially psychotropic drugs were dealt with under by the Drug Enforcement Commission (DEC). Mr. Osborne Kamwale<sup>32</sup> an inspector who has served both under the 'Pharmacy and Poisons Board' and currently under the 'Pharmaceutical Regulatory Authority' indicated that the defunct regulatory body seemed not to have enough teeth to bite. There were times when they would start a case but down the line they would be advise that what they wanted to do against such offenders was not backed by the law. He indicated that with the current law, most of the usual offences are clearly outlined together with their respective sanctions.

Under the old law, inspectors from the regulatory authority carrying out inspections then were supposed to pay for any samples taken from the market for verification. Under the current law an inspector can take as many samples as he deems reasonable for the purpose of carrying out his or her duties<sup>33</sup>. The paying for samples in a way hindered the work of the inspectors then due to the financial constraints especially where medicines were expensive. The previous law was also weak because it did not provide for clear sanctions such as penalty units or imprisonment. It made operations so weak and demoralised greatly any shade of enthusiasm towards work by its officers. Mr. Kamwale went further to state

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<sup>32</sup> Interview: O. Kamwale, 4/02/2011

<sup>33</sup> Section 60, Pharmaceutical Act

that most cases that reached litigation were based on the Penal Code. The ‘Pharmacy and Poisons Board’ would only report persons found in possession of government medicines to the police who dealt with them under the attorney general’s office for theft under the Penal Code Act, Cap 87 of stealing government property<sup>34</sup>. The police would be the ones in the fore front for such cases. Currently, the ‘Authority’ has powers to sue and so it is capable of prosecuting cases on its own<sup>35</sup>.

In an interview with the Pharmaceutical Regulatory Authority’s director of inspections, Mrs C. Yeta, it was indicated that the task of enforcing the legislative requirements regarding pharmaceutical products and allied substances was huge and demanding because the institution had few inspectors and the public generally was not so forth coming as regards reporting cases of illegal trading in pharmaceutical products in the community<sup>36</sup>. So far, the Pharmaceutical Regulatory Authority has been working hand in hand with the Zambia Police and the Drug enforcement commission in following up on any reports related to abuse or illegal handling of pharmaceutical products and allied substances, and any concerns that relate to the functions of the Pharmaceutical Regulatory Authority.

The *pharmacovigilance* unit of the Ministry of Health has also been working together with the Pharmaceutical Regulatory Authority to ensure safety of citizens in the area of adverse reactions to drugs on the market.

In a survey carried out by medicines transparency alliance of Zambia, it was noted that the Pharmaceutical Act, No.14 of 2004 was well placed in Zambia compared to the previous

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<sup>34</sup> Section 265, Penal Code Act, Cap 87 of the laws of Zambia

<sup>35</sup> Section 4 (1), Pharmaceutical Act

<sup>36</sup> Interview: C. Yeta, 7/11/ 2010.

law in terms of current pharmaceutical industry's needs<sup>37</sup>.

The Pharmaceutical Regulatory Authority is mandated as observed in the chapter two to inspect registered and unregistered premises where the business of pharmaceutical and allied substances is conducted. There is also a policy under the Ministry of Health for the Pharmaceutical Regulatory Authority to inspect all public sector pharmaceutical outlets but regulations have not been put in place<sup>38</sup>.

### **3.2 Herbal medicines under the Pharmaceutical Act No14 of 2004**

The regulation of herbal medicines and other related products is another new area which was never under stringent regulatory control. The 'Authority' has a mandate to make regulations relating to the use, supply and distribution of herbal medicines and related products<sup>39</sup>. The repealed laws relating to the regulation and control in the pharmaceutical industry did not cover this area of pharmacy. The Pharmacy and Poisons Act of 1941 applied specifically to certain 'poisons' listed under part IV<sup>40</sup>. The minister from time to time would include new substances to the list of the regulated chemicals but herbal products were never considered.

A senior pharmacist<sup>41</sup> from the 'Pharmaceutical Society of Zambia' commented that, more people are being convinced by healthy-living advocates, some health practitioners and those in the fashion-world to take up more of herbal based medicines and remedies than the well-known conventional medicines as they are claimed to be the best for a healthy body.

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<sup>37</sup> Medicines Transparency Alliance Zambia. *Disclosure Status of pharmaceutical sector data, part of component 1 of the MeTa baseline Assessments*, Zambia June 2010, p10

<sup>38</sup> Section 29, Pharmaceutical Act

<sup>39</sup> Section 6(1)(a), Pharmaceutical Act

<sup>40</sup> Section 11(4), Pharmacy and Poisons Act

<sup>41</sup> Interview: D. Nguni, 15/12/ 2010

There is an influx of herbal based medicines and remedies on the market. The cosmetics range has also not been left out in this herbal-race. He indicated that, it makes sense then to have this area regulated more stringently like conventional medicines to safe guard the public from unscrupulous dealers who would actually be dealing in materials that have no therapeutic properties or benefits to the body, or worse still substances that could be very toxic to the body leading to serious harm to the body or even death of unsuspecting customers.

Under the 'Pharmaceutical Act', all dealers in herbal medicines are required to be registered and pack their products in a specified acceptable manner as prescribed by relevant regulations. To grant a permit or licence to carry on business in herbal products, the Pharmaceutical Regulatory Authority will have to carry out tests on the materials to check for the claimed efficacy and toxicity through research and clinical trials. This would be done in the same way the Sondashi formula<sup>42</sup> was treated in 2008, when its claim of the effect on the HIV virus was put to the test by a research team in conjunction with the National Aids Council.

The only challenge in the area of herbal remedies would be to regulate traditional healers. Majority of the traditional healers in Zambia just inherited the knowledge they have for what they administer from their fore-fathers and may not explain to you how the medicine they administer works. The other factor is that most of them are illiterate and to appreciate issues of regulation would be like attempting to block them from utilising what God has given them. Despite all this expected resistance, regulations must be in place to safe guard the public

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<sup>42</sup> Sondashi2000, a herbal product sold by a prominent Lusaka lawyer Dr. Ludwig Sondashi to people living with HIV so that the immune system is boosted.

The 'Pharmaceutical Act' describes herbal medicine as:

'Any medicinal product that contains, as active ingredients, aerial or under ground parts of plants, other plant materials or combinations thereof, whether in a crude state or as plant preparations and includes herbal medicines which contain natural, organic or inorganic active ingredients ..'<sup>43</sup>.

The challenge of the 'Authority' is huge where control of the use, sale and supply of herbal based products is concerned. Work would start becoming easier once the national drug quality control laboratory becomes fully functional in the course of this year where most of tests shall be carried once facilities are in place<sup>44</sup>.

### **3.3 Review of some cases handled by the Pharmaceutical Regulatory Authority related to the Pharmaceutical Act No.14 of 2004**

A review of cases handled by the directorate of inspections of the 'Authority' shows some appreciable activity than it used to be under the defunct 'Pharmacy and Poisons Board'. The following cases<sup>45</sup> will give an insight of the work of the Pharmaceutical Regulatory Authority in bringing sanity to the pharmaceutical industry.

A review of cases from January 2008 to December 2009 shows that a number of businesses had been operating illegally without following established laws. This had been rampant especially in areas away from main business centres in different towns and cities.

Most cases that have arisen are to do with illegal trading in unregistered medicines and

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<sup>43</sup> Section 2, Pharmaceutical Act

<sup>44</sup> The Director General of the Pharmaceutical Regulatory Authority addressing employees of the National Drug Quality Control laboratory, 6<sup>th</sup> January 2011

<sup>45</sup> Report on cases handled by the Pharmaceutical Regulatory Authority. By C. Yeta; 17<sup>th</sup> January 2009

allied products, trading without a licence and impersonation as authorised persons to carry on the business of pharmacy. The Pharmaceutical Regulatory Authority with the mandate under the 'Pharmaceutical Act' has taken up the challenge to start enforcing the law and regulations and apply sanctions were necessary.

### **3.3.1 The People v Lusaka Madi Camp Limited and Others<sup>46</sup>**

Lusaka Madi Camp Limited and Others pleaded guilty to offences committed under the 'Pharmaceutical Act'. The company and others were convicted by the Lusaka magistrate court on charges of importing unregistered medicines contrary to section 40(1) of the 'Pharmaceutical Act' in the first count. In the second count the company was also convicted on charges of labelling medicines in a false and misleading manner contrary to section 35(1) of the 'Pharmaceutical Act'. The company was fined and in addition, the pharmacist and the three directors were given six months sentence suspended for two years. An order was also made to forfeit the medicines to state for disposal.

Being a private company and not necessarily dealing in government medicines, it would have been difficult under the old law to prosecute such a case. Under the current law this is possible

### **3.3.2 The People v Kaluba Kampamba<sup>47</sup>**

Kaluba Kampamba, of Lubuto west in Ndola was arrested as part of the joint operations between the Pharmaceutical Regulatory Authority and the Zambia police. He was found running an illegal drugstore and was in possession of medicines for the government. Kampamba was indicted for operating a pharmacy without a pharmacy certificate and

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<sup>46</sup> 8<sup>th</sup> April 2008, unreported

<sup>47</sup> 21<sup>st</sup> May 2008, unreported

pleaded guilty to the charge in the Ndola magistrate court. He was fined K9 million and sentenced to seven months imprisonment in default. However, Kampamba failed to pay the fine and was taken in to serve the custodial sentence at Kansenshi prisons in *Ndola*.

Previously, only one case could have had arisen of having in possession of government property and dealt with under the penal code. The 'Pharmaceutical Act' as was applied here put sanctions on both charges of an illegal drug store and in possession of medicines.

### **3.3.3 The People v Sigma Investment Limited<sup>48</sup>**

Sigma Investments Limited of Kabwe was charged with operating a retail pharmacy without a pharmacy certificate contrary to section 14(1) of the 'Pharmaceutical Act'. The court fined the company K9 million.

### **3.3.4 The People v Medmate Limited<sup>49</sup>**

Medmate Limited, another company from Kabwe was charged with an offence of operating the business of retail pharmacy without a licence issued by the Pharmaceutical Regulatory Authority. The court convicted and fined the entity K9 million.

### **3.3.5 The People v Pandor Muhammad<sup>50</sup>**

Pandor Muhammad was charged in Mumbwa with an offence of operating a business of a retail pharmacy without a pharmacy certificate issued by the Pharmaceutical Regulatory Authority contrary to section 14(1) (2) of the 'Pharmaceutical Act'. He pleaded guilty, then he was convicted and fined K9 million.

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<sup>48</sup> 6<sup>th</sup> June 2008, unreported

<sup>49</sup> 6<sup>th</sup> June 2008, unreported

<sup>50</sup> 11<sup>th</sup> December 2008, unreported

### **3.3.6 The People v Chachacha Healthcare Limited<sup>51</sup>**

This is a case in which Chachacha Healthcare Limited was charged with an offence of supplying unregistered medicines contrary to the provisions of the law<sup>52</sup>. The company supplied unregistered medicines to the University Teaching Hospital. The company was convicted by the Magistrate Court in Lusaka, and fined K11 million and 36 months imprisonment sentence for the directors if the company defaulted.

### **3.3.7 The People v Trywell Zebron Tembo<sup>53</sup>**

Trywell Zebron Tembo was charged by the Pharmaceutical Regulatory Authority for operating the business of a retail pharmacy without a pharmacy certificate contrary to section 14(1) (2) of the 'Pharmaceutical Act'. He was also charged with another offence of carrying on a business of pharmacist without conspicuously exhibiting on the premises the name and certificate of registration of the person having control of the business contrary to section 15 of the 'Pharmaceutical Act'. He was found with a case to answer and was put on his defence. However; before Tembo could open his defence, the case was discontinued when the state entered a *nolle prosequi*.

### **3.3.7 The People v Juster A. Mukwala<sup>54</sup>**

Juster Mukwala was charged with an offence under the 'Pharmaceutical Act' of manufacturing, importing, exporting, distributing and selling of substandard counterfeit medicines and allied substances contrary to section 33 (1). He was convicted and sentenced to 5 years imprisonment with hard labour.

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<sup>51</sup> 19<sup>th</sup> June 2008, unreported

<sup>52</sup> Section 40 (4), Pharmaceutical Act

<sup>53</sup> 8<sup>th</sup> December 2008, unreported

<sup>54</sup> 11<sup>th</sup> June 2008, unreported

### **3.3.8 The People v Live Stock Services Limited**

Live Stock Services Limited, a Lusaka based company was found with an offence contrary to section 34 (1) (2) of the 'Pharmaceutical Act'. The company was found selling expired medicines at their registered premises. The accused entity was acquitted on the charges after the prosecution team failed to adduce sufficient evidence.

## **3.4 Public awareness of the enforcement of the Pharmaceutical Act No.14 of 2004**

From the cases so far dealt with by the Pharmaceutical Regulatory Authority, one would clearly see that some stake-holders in the pharmaceutical industry had not taken legal requirements in conducting their business seriously. This lack of seriousness in abiding by the laws could have been due to various factors. Among these could be that the repealed law<sup>55</sup> had enforcement weaknesses or that the institution then mandated to ensure the law was applied could have had some weaknesses in its operations. With reports on the activities of the Pharmaceutical Regulatory Authority being made public<sup>56</sup> as observed in the survey carried out by the medicines transparency alliance, people would be deterred from engaging in illegal businesses in the pharmaceutical sector as there are stiffer penalties once convicted. This will also help professionals licensed to practice in this sector to observe their professional ethics and in the end protect the public from the supply of unsafe medicines and allied products.

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<sup>55</sup> Pharmacy and Poisons Act Cap 299, 1940

<sup>56</sup> Medicines Transparency Alliance Zambia. *Disclosure Status of pharmaceutical sector data, part of component 1 of the MeTa baseline Assessments, Zambia* June 2010, p10

At the rate at which the Pharmaceutical Regulatory Authority is expanding, more impact of its presence is likely to be felt as it enforces the legal provisions of the 'Pharmaceutical Act'. In December 2010, the institution recruited more inspectors for both the product registration and inspection directorates, and pharmaceutical analysts for the laboratory services directorate whose laboratory is based at the National Institute for Scientific Research<sup>57</sup>, Lusaka, which is due to be launched before the close of this year, 2011.

The next chapter examines the impact of the 'Pharmaceutical Act' on the pharmaceutical industry and pharmaceutical companies operating in Zambia.

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<sup>57</sup> Interview: M. Banda, 6/01/2011

## **CHAPTER FOUR**

### **4.1 The Pharmaceutical Act No.14, 2004 and the Pharmaceutical Industry in Zambia.**

As indicated in chapter one, the pharmaceutical industry has had a noticeable growth since the liberalisation of the economy by the Movement for Multiparty Democracy (MMD) that came to power in 1991. Initially the industry was largely dominated by drug outlets run by business men and women of Asian origin representing Indian pharmaceutical manufacturing companies,

Currently the industry has recorded the presence of products from China, Europe, the USA and other African countries. With more Zambians qualifying as pharmacists mainly due to the opening of school of pharmacy at the University of Zambia, a number of drug outlets have been opened and being run by indigenous Zambians especially outside main business centres of cities and towns. On the hand the pharmaceutical manufacturing sector has not grown so much as compared to a number of foreign manufactures who have penetrated the industry with their products.

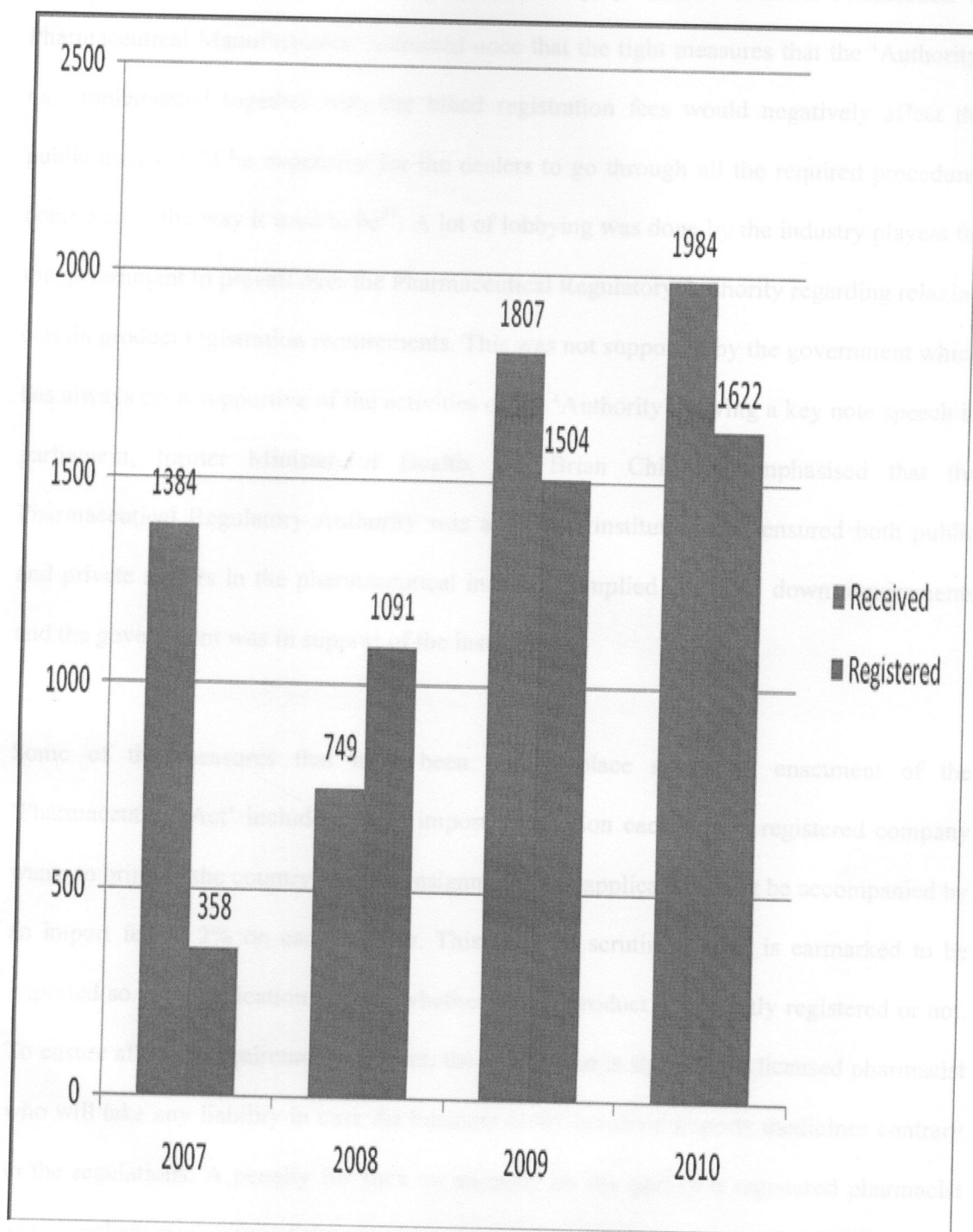
With the enactment of the 'Pharmaceutical Act' and its implementation by the Pharmaceutical Regulatory Authority, there has been a sigh of relief from genuine businesses dealing in pharmaceutical products and allied products. This is because of so much vigilance and consistency in monitoring of market players by 'Authority' in ensuring that who ever is dealing in this area of the economy has the necessary licences.

The 'Authority' has indicated that, there has been an increase in the number of registered products and those that are retained each year from the inception of the Pharmaceutical

Regulatory Authority.

From the table below, the number of products received and registered from 2007 to 2010 has seen a general increase. The positive situation could be that companies in the industry are appreciating to work within the law and are eager to bring in more products because the environment is well regulated for making a return on their investment. The effort that the 'Authority' makes in ensuring that only products that satisfy all the legal requirements can be seen from the difference in the number of products that have been tendered for registration and those that are actually given licence numbers. The scrutiny that is carried out ensures that only safe and efficacious drugs are allowed on the market. Section 37 of the 'Pharmaceutical Act' empowers the 'Authority' to screen thoroughly all registration applications.

TABLE 1: Products received for registration and those given licences from 2007 to 2010<sup>58</sup>



<sup>58</sup> Directorate of Registration at the Pharmaceutical Regulatory Authority; February 2011

The sudden change in the levels of inspections and vigilance in the pharmaceutical industry still brought some apprehension among business players. The 'Zambia Association of Pharmaceutical Manufacturers' indicated once that the tight measures that the 'Authority' has implemented together with the hiked registration fees would negatively affect the public as it would be expensive for the dealers to go through all the required procedures compared to the way it used to be<sup>59</sup>. A lot of lobbying was done by the industry players for the government to prevail over the Pharmaceutical Regulatory Authority regarding relaxing certain product registration requirements. This was not supported by the government which has always been supportive of the activities of the 'Authority'. Giving a key note speech in parliament, former Minister of Health, Dr. Brian Chituwo, emphasised that the Pharmaceutical Regulatory Authority was a vigilant institution that ensured both public and private sectors in the pharmaceutical industry complied with laid down requirements and the government was in support of the institution<sup>60</sup>.

Some of the measures that have been put in place since the enactment of the 'Pharmaceutical Act' include a fresh import application each time a registered company wants to bring in the country a new consignment. The application must be accompanied by an import fee of 2% on each invoice. This helps to scrutinise what is earmarked to be imported so that verification is done whether such a product is currently registered or not. To ensure all legal requirements are met, the application is signed by a licensed pharmacist who will take any liability in case the business entity involved imports medicines contrary to the regulations. A penalty for such an anomaly on the part of a registered pharmacist would include revocation of the practising licence and possibly banning such an individual

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<sup>59</sup> Interview: Mr. Murugapan, 12/12/2010

<sup>60</sup> Daily Parliamentary Debates, Thursday, 9<sup>th</sup> August, 2007

[http://www.parliament.gov.zm/index.php?option=com\\_content&task](http://www.parliament.gov.zm/index.php?option=com_content&task) date accessed: 22/12/2010

from practice for life. This kind of measure has in the end increased compliance among industry players.

The other aspect that brought tension on implementation was the introduction in 2007 of the requirement to stamp all registered products with their product registration numbers for easy trace in case of a problem. Most multinational manufacturing companies whose products are on the Zambian market supplying drugs from *Antiretrovirals* to *Antimalarials* complained about the measure. They claimed that their batch sizes of products catered for many countries and it would be expensive for them to change their packing lines just to suit Zambia which was a small market for them. Some companies including Dafra pharma of Belgium which supplies an effective antimalarial *Arinate* and *Cipla Ltd* of India the supplier of *Trimune* one of the first line antiretroviral drugs, lodged complaints through their local agents then Pharco Limited and Melcome Pharmaceuticals respectively and threatened to withdraw their products from Zambia but that did not shake any one. All this blackmail was ignored by the 'Authority' which was determined to implement the regulations in bringing the necessary control just like in any progressive country. The 'Authority' only allowed them to use the already imported products within 12 months and later comply with the measures.

The local manufacturing sector has not been spared with the need to abide by the law as provided in the 'Pharmaceutical Act' and other relevant regulations. The Directorate of inspections has ensured routine inspections in the pharmaceutical manufacturing facilities for compliance with laid down guide lines of good manufacturing practices.

To ensure that the public is aware about the existence of the Pharmaceutical Regulatory Authority, there are several programs that have been put in place. In conjunction with Zambia National Broadcasting Corporation, the 'Authority' hosts public awareness and sensitisation phone in radio programs in English and local languages. This effort has already received good response based on the participation from listeners<sup>61</sup>.

Despite receiving negative all these challenges from some industry's players, the Pharmaceutical Regulatory Authority has also received support in some circles. One of such concerns has been the lack of the board since the 3 year term of the first board expired. The publicity secretary of the Public Health Partnership Forum, Enock kaputula bemoaned the lack of a board to oversee the running of the Pharmaceutical Regulatory Authority<sup>62</sup>. He wondered why the Health Minister had not appointed the board as provided for under section 8 of the 'Pharmaceutical Act' The Health Partnership Forum (PHPF) also appealed to the government to speed up the setting up of the National Drugs Quality Control Laboratory which would be tasked to verify the safety and quality of drugs manufactured and imported in the country. Mr. Kaputula indicated that:

"... it is sad that at the moment the medicines or drugs that are on the Zambian market are not tested due to the absence of a national drugs quality control laboratory in the country..."

This concern has since been given attention as the establishment of the medium size laboratory before the close of this year 2011 is likely to be done at the National Institute for Scientific Research on International Airport Road in Lusaka. This is in fulfilment of the provisions in the 'Pharmaceutical Act'<sup>63</sup>.

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<sup>61</sup> Interview: Mrs. C. Yeta, 2/2/ 2011.

<sup>62</sup> Times of Zambia, Monday October, 4, 2010

<sup>63</sup> Section 57

With the relationship created between the Pharmaceutical Regulatory Authority and the pharmaceutical industry in Zambia; a common goal through the implementation of the provisions of the 'Pharmaceutical Act' is likely to be achieved. Despite being the regulator, the 'Authority' has at different forums lobbied the government to provide certain incentives to the industry to attract more players especially in the manufacturing sector so that the country benefits from its own regulated medicines<sup>64</sup>.

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<sup>64</sup> Interview: E. Mwape, 13/12/2010

## CHAPTER FIVE

### 5.1 Conclusion

The rebirth of the multiparty democracy era in 1991 which saw the Movement of Multiparty Democracy (MMD) taking over from the United National Independence Party (UNIP) changed the economic environment in Zambia. The new government liberalised the economy encouraging private entrepreneurs. The pharmaceutical sector was one such sector. The increase in the activities in the pharmaceutical sector required relevant applicable laws of the time to regulate the industry.

The enactment of the Pharmaceutical Act No.14 of 2004 brought a different direction to the regulation of the pharmaceutical industry in Zambia. From independence, the country has been using the repealed laws borrowed from Britain. The law that applied prior to the enactment of the 'Pharmaceutical Act' lacked enforcement and powers to sanction offenders by the regulating institution. The defunct 'Pharmacy and Poisons' was not a body corporate but a government department in the Ministry of Health. It had no powers to sue on its own but largely depended on the police to prosecute cases that came before it. With the already overwhelmed cases with the police service, a number of cases could drag for a long time before they could be disposed off or even ended in acquittals because of lack of relevant laws for offences related to medicines and allied substances. The defunct 'Pharmacy and Poisons Board' which applied the 'Pharmacy and Poisons Act, 1940' and the 'Therapeutic Substances Act, 1968' basically had no teeth to regulate the pharmaceutical sector where sanctions are concerned.

The Pharmaceutical Regulatory Authority which has replaced the 'Pharmacy and Poisons Board' through the enactment of the 'Pharmaceutical Act' has made an impact in the pharmaceutical industry. A number of cases have been prosecuted by prosecutors from the

‘Authority’ who are full employees without necessarily depending on the Zambia police as it used to be before. The cases noted in this research show that the new law is effective in the regulation of the industry as it has sanctions in all areas that require licences. It is not usual to day especially in major cities to find one running an illegal drug store without being visited by inspectors from the ‘Authority’. The sanctions being applied once convicted under the ‘Pharmaceutical Act’ have a deterrent effect which sends as a warning to would be offenders.

It suffices to indicate here that from the findings in this research, the Pharmaceutical Act No.14 of 2004 has so far been effective in the way it has been applied by the Pharmaceutical Regulatory Authority compared to the weak effect that the repealed laws had on the industry.

## **5.2 Recommendations**

As noted, the pharmaceutical industry is still in its infancy. As it expands with the current enabling environment for investment, the ‘Authority’ requires to have enough qualified manpower was once emphasised by Dr. Chipayeni Mtonga, Health Officer in charge of Health Systems at the WHO country office <sup>65</sup> to ensure that the industry is well regulated throughout the country.

There must be a deliberate policy by the government to ensure that officers at the ‘Authority’ receive the necessary training to much with standards of other well organised pharmaceutical regulatory authorities in the world.

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<sup>65</sup> MSH: Quality Assurance of Medicines in Zambia - An Assessment Visit to the Zambia Pharmaceutical Regulatory Authority: Trip Report, p 9

All the border points into Zambia require the presence of inspectors from the 'Authority' so that only registered medicines and allied substances enter the country.

The government need to fully support the establishment of the national quality control laboratory by the 'Authority' so that evaluation of the quality of medicines become easier.

The government need to increase its funding to the 'Authority' for it to implement various planned activities for community awareness and enforcement of the prescribed laws and regulations.

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