

THE IMPACT OF DRUG ABUSE ON THE  
MARKETING OF PHARMACEUTICAL  
PRODUCTS IN NIGERIA

A CASE STUDY OF ROCHE (NIGERIA) LIMITED  
AND THE BENZODIAZEPINES

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**CERTIFICATION**

This Project has been read and approved as meeting the requirement of the Post Graduate School and the Department of Business Administration, Ahmadu Bello University, Zaira for the award of master of Business Administration (MBA)

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## **DEDICATION**

This Project is dedicated to my daughter Abigail Ebuwe and my wife Christy Ojoru; they made unflinching sacrifices and were sources of my inspiration. I thank you for your love, support and understanding on those occasions I had to leave you alone and travel for the weekend in Zaira.

## DECLARATION

I hereby declare that this project is purely my work and has to the best of my knowledge never been published before.

All works consulted have been acknowledged accordingly in the bibliography.

  
ABALAKA, AD.

## ACKNOWLEDGMENT

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## **ABSTRACT**

This study attempts to relate theory to practice. Drugs have been used by various societies in the world to relieve pain, alter perception and also provide pleasurable sensation. However where they are not used correctly, they produce unpleasurable consequences. For this reason there are international conventions and local regulations that govern the sale of drugs. This is especially more important for psychotropic drugs whose abuse has great psychological consequences.

Roche (Nigeria) Limited is a company in the forefront of research, production and marketing of Benzodiazepine, a class of psychotropic drugs.

The study attempts to understand Roche (Nigeria) Limited, its operations and marketing activities in respect of Benzodiazepines vis-a-vis the pressure by regulatory agencies which is likely to have impact on the sale of these products. The study reveals the trend analysis of the sales performance and the impact of these controls over a 5 - year reviewed period.

Thus, the study is investigative in nature and makes recommendations to the company on appropriate marketing

strategies to enable it contain the regulatory environment without jeopardizing her marketing objectives.



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# CHAPTER 1

## INTRODUCTION

### 1.1 INTRODUCTION

A drug is any substance which when taken into the living organism may modify one or more of its functions.

The Oxford Dictionary defines drug as a simple Medicinal substance used by itself or as an ingredient in Medicine.

The World Health Organisation (WHO) expert committee on essential drugs define **DRUGS** as any substance in Pharmaceutical product that is used to modify or explore physiological systems or pathological states for the recipient.

The poision and pharmacy act cap 152, 1964 of Nigeria defines Drug as including any substance of vegetable, animal or mineral origin used for external or internal application to the human body in the treatment of disease.

These are a few definitions of the term Drug. Essentially, drugs are

invaluable in the treatment of diseases for the control of disorders and discomfort and for the alleviation of pain in man and animals if properly handled. Thus, a drug is usually applied for therapeutic purpose (s). However, when used wrongly deliberately or inadvertently, it gives rise to Economic and Psychosocial concerns.

The societal discomfort that arises from this is responsible for the magnitude that the subject of Drug abuse has assumed today worldwide.

The choice of this topic is thus to study the issue of Drug abuse critically as it relates to a particular class of drugs manufactured and marketed by Roche (Nig) Ltd and its attendant implications on the marketing practices.

## 1.2 **MARKETING DEFINED:**

As remarked by Peter Drucker (1954) there is only one valid definition of business purpose: to create a satisfied customer. It is the customer that determines what the business is. Because it is its purpose to create a customer, any business enterprise has two and only two basic functions, *marketing and innovation*. Marketing is the whole business seen from the point of view of its final result, i.e. from the customers point of view.

Peters and Waterman (1982) further agreed that market orientation is the most effective way to achieve long run profitability. The interests of the customer are therefore considered to be the first and foremost priority of the firm. Success will come through determining what customers really want, that is 'needs' defined from the customers point of view.

For a company to secure its objectives, it must satisfy customer needs better than the competition and at a profit.

A truly market - oriented company is one where not only the marketing but also Research and Development, registration, finance, planning and production personnel approach their task from the point of view of producing the best possible value for the customer.

## **FURTHER DEFINITIONS OF MARKETING:**

Human activity directed at satisfying needs and wants through exchange process - Kotler.

A thin line exists between marketing and selling as stated by Levitt (1960)

“The difference between marketing and selling is more than semantics. Selling is preoccupied with the seller's need to convert his products into cash and marketing with the idea of satisfying the needs of the customer by means of the product and the whole cluster of things associated with creating, delivering and finally consuming it”.

The organisation should determine / understand the needs, wants and interests of the target market and deliver the desired satisfactions more effectively and efficiently than competitors in a way that maintains or improves the customers' and the society's well being.

Marketing mix is defined as “the set of controllable variables that a company can use to deliver (utility) to the customer and with which to influence the customers response”

**They include:**

➤ **Product**

The benefits or positive results that markets derive out of doing business with the company using the product offered in the way they are offered.

➤ **Place**

The distribution channels and physical distribution practices that make it possible for markets to use the product.

➤ **Price**

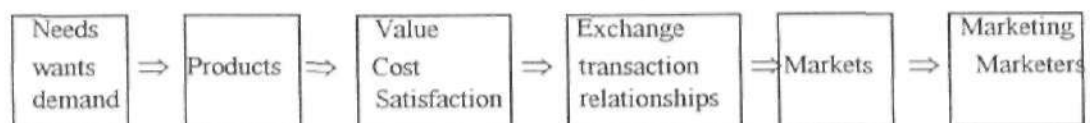
The total cost components that markets must bear in order to sell the products offered.

➤ **Promotion**

What and how markets are informed of the firms products.

Kotler again looked at Marketing as “ a social and management process by which individuals and groups obtain what they need and want through creating, offering and exchanging products of value with others”.

The core concepts are represented as:





**A product** is anything that can be offered to someone to satisfy a need or want.

**Transaction** consists of a trade of values between two parties and differs from one to another.

**Markets** consists of all the potential customers sharing a particular need or want who might be willing and able to engage in exchange to satisfy that need or want.

The American marketing association defines marketing management as the "Process of planning and executing the conception, Pricing, Promotion and Distribution of ideas, goods and services to create exchanges that satisfy individuals and organisational objective".

Under the marketing concept, the key to achieving organisational goals consists in determining the needs and wants of target markets and delivering the desired satisfactions more effectively and efficiently than competitors. Thus to operate this concept, a company must have a market focus since no company can operate in every market and satisfy every need. Companies do best when they define their target markets carefully and they prepare a tailored marketing programme for each target market.

Customer orientation require and assists a company to define customer needs from the point of view of the customer, since company sales are expected from customers ( new or repeat customers).

A coordinated marketing programme is critical to achieve set objectives.

Finally it must be understood that the marketing concept helps organisation to achieve their goals and for private firms, a major goal is profit.

### 1.3. CHARACTERISTICS OF THE PHARMA INDUSTRY:

The pharmaceutical industry is a specialized industry with the following characteristics as identified by M. Smith.

**Customers** - Large population, complex processes; the prescribers and users do not belong to same economic unit.

**Products** - Small transactions for relatively high unit cost. High risk involved. Health is concerned (ethical dimension is introduced into business) Good marketing and good medicines are not only compatible, they are inseparable.

**Regulation** - Extensive set of laws and regulations govern the business. Patients are crucial, regulation touches on all the elements of the marketing mix.

**Research and Development-** Complex, risky, venturesome and essential for new products. A lot of 'trial' and 'error' research approach. Development is complicated because new products have to be tested on humans.

Thus, with low prescription volume, growth and government control, revenue growth can only be achieved by the displacement of competing products and innovation beyond competing products - innovation is thus the lifeblood of the research based pharmaceutical industry.

Drugs affect and alter health. By their very nature, they play a prominent role in the society.

The drugs (pharmaceutical) industry consequently also plays a prominent role. The president of one of the largest pharmaceutical manufacturer has defined the role to include:

- Discovery and development of new drugs.
- Rapid and safe development of these drugs into useful and therapeutic tools and
- Production and distribution of safe and efficient existing drugs.

Pharmaceutical marketing as a subspecialty of marketing can therefore be defined as "a process by which market for pharmaceutical care is actualised". The emphasis in Pharmaceutical marketing is on pharmaceutical care, and not just in drugs. The justification of its existence is the patient and not the manufacturer.

**The environment of the pharmaceutical marketing include:**

- Technological
- Political
- Economic
- Social
- Legal / Regulatory

In the industry, to out perform competitors and grow despite them, a company must understand why competition prevails, why firms attack and firms respond.

### **TECHNOLOGY ENVIRONMENT.**

The Pharmaceutical industry lives and thinks because of technological advances in therapy. Technology evolves which at least influences and at times transforms the character of the industry. The technologic environment is broader than within the industry itself. Thus the marketing planner must mount a

systematic technology scanning program to identify both potential problems and opportunities.

### **POLITICAL ENVIRONMENT**

Political trends are more important where governments are weak than where they are strong, yet in the later political trends have a significant impact on business. Overseas and global trends are also important because of the dependence of the economy on that of Europe, US and other African and Asian countries. The marketing strategist therefore needs to study both domestic and foreign political happenings as it relate to a particular company.

### **ECONOMIC ENVIRONMENT**

Economic trends and event affecting business are analyzed since the macro economic variables are very important to individual firms planning.

### **THE LEGAL AND REGULATORY ENVIRONMENT.**

The thalidomide tragedy of early 1960s is the most important event in the history of the industry as the legal / regulatory environment is concerned and played a key role in strengthening various laws and increased regulatory powers on drugs internationally.

The legal and regulatory issues perhaps as much as or more than any of the other environmental factors must be assessed as part of the strategic marketing process.

Regulation has significant economic effects as provided by Douglas Cocks, an economist on the pharmaceutical industry in the U.S which includes.

- \* Supply side regulation - social opportunity cost, reduced innovation for consumers, concentration of business in a few large multinational firms and shortened patent life.
  
- \* Demand sides regulation - lead to constrained use of certain products. The effects are usually long run. They affect the internal markets and cash flows as primary source of pharmaceutical research and development, thus Research and Development activities is reduced.

As remarked by Earnest Mario, the Deputy Chairman of Glaxo US (1989) "the laws of the market place now apply to as much the pharmaceuticals as to consumer of Electronics. Once armed with a new product, a company establish its market share as quickly as possible before rival firms produce competitive brands".

This is significant to consider in the discussion of the topic of pharmaceutical marketing.

### **SOCIAL ENVIRONMENT.**

Social relevance is the ultimate test of a business. The strategic planner must thus be familiar with emerging trends and concerns. These informations are derivable from published sources. It is most important to be proactive in planning.

Competitive intelligence involving insights into the competitors perspectives can be gained by understanding two types of analysis

- Industry
- Competition

### **1.3.1. THE PHARMA INDUSTRY AND THE DISTRIBUTION CHAIN**

The Pharmaceutical Industry would include all those institutions and agencies involved in the production and marketing of medications and on a narrow basis could be described in terms of those firms engaged in the manufacture of pharmaceuticals.

Usually there are many buyers between Pharmaceutical manufacturers and the ultimate consumer of his products. The consumer is therefore not a direct customer of the manufacturer and for regulatory reasons, many of the products cannot be promoted directly to the consumer and indeed promotion are usually targeted at the different points on the chain.

The customers include:

- Wholesalers
- Retail Pharmacies
- Health Establishments / Agencies
- Hospitals.

**Wholesaler** - The most important class of buyers. The highest proportion of direct sales from manufacturers occur through this source.

**Retail Pharmacies** - Large numbers and usually a direct contact exist between patient and the product at this stage. They are direct customers of the wholesaler. Indeed "the relationship between the supplier and the retailer always has been a struggle for power; a tug-of-war pitting the suppliers need for shelf space and distribution against the retailers need to remain competitive in its inventory assortments one-stop category appeal to its customers."

**Health Establishments / Institutions:** are involved in direct purchase of drugs for their patients and include Government Health Units and Corporations.

### **Hospitals**

Other than retailers, Hospitals are by far the largest dispensers of drugs. The physician is the orderer of the drug. The efficient operation of a Hospital is dependent on the cooperative efforts of many types of Health professionals such as physicians, nurses, pharmacists and lab technicians. Hospital Formulary inclusion is a key to the success of introductions of Hospital based products.

#### **1.3.2 THE MICRO ENVIRONMENT OF THE INDUSTRY.**

This consists of the different factors directly interfering with the industry.

- The Buy as discussed under the distribution channel.
- Suppliers whose services and products are assets when available and an impediment when they cannot be obtained (especially pharmaceutical technology and information).
- Substitutes - which threaten the pharmaceutical market and include:
  - \* Substitution of an original chemical entity with a generic version
  - \* Substitution of a product type or class with a chemically different but pharmacologically similar product.
  - \* Substitution of medication with a non-medication treatment or preventive measure.
- Potential entrants  
Competitive analysis requires their assessment at two levels.
  - \* entrants with pharmaceutical experience
  - \* entrants without pharmaceutical experience.



This is very essential because the pharmaceutical industry is one of high risk, great capital requirements and a long period of pay off at least for new drug developments.

#### **1.4. PROBLEM DEFINITION**

This research is directed at Roche (Nigeria) Ltd to determine the kind of marketing strategies to apply to ensure that the influence of various regulatory controls on the distributive channel does not have negative impact on her marketing activities. The National Agency for Foods, Drugs administration and Control (NAFDAC) and The National Drug Law Enforcement Agency (NDLEA) are Government Agencies charged with the responsibilities of Drug control in Nigeria. Over a five year period (1993-1997), they have implemented different programmes at stemming the abuse/illicit use of phychoactive drugs. Some of these measures have sent 'Panic' to the distribution channel, to the extent that trading activities in Benzodiazepines are almost being carried out clandestinely. This is unfortunate as duly registered and authorised pharmacy outlets are entitled to selling these drugs in accordance with specified provision under the relevant laws.

Drug abuse has a very significant psychosocial problem and thus the interest of NAFDAC and NDLEA in containing it. The activities of these agencies is a result of their quest to prevent the phenomenon. A range of behaviour modification as result of drug abuse include, physical dependence, drop out in school, man hour loss, psychological dependence, truancy, armed robbery etc.

For Roche, Benzodiazepine range of drugs is a class of drugs that is very critical to the company operation. Over the period of review, they account on annual basis over 20% of her turnover and rank number 2 in the product portfolio when considered in terms of total company sales. Any significant negative impact on these drugs will therefore result in serious adversity to the operation of the company.

For the purpose of comprehension, Lexotan is a drug in this class that contributes over 80% of the sales contribution from the Benzodiazepines and the most important singular drug. It's fortune over the period has been selected for the study.

Therefore, it is the aim of this study to suggest marketing strategies through which manufacturers and registered and authorised pharmacy outlets can employ in the marketing of drugs that are common abuse interms of usage.

### **1.5. AIMS AND OBJECTIVES OF THE STUDY**

1. Determine the regulatory controls by NAFDAC and NDLEA on the marketing and sales of Benzodiazepines in Nigeria in the period 1993 - 1997.
2. Determine the sales performance for Roche (Nig) Ltd in respect of lexotan in the period 1993 -1997 and determine the impact or otherwise of (1) above.
3. Recommend means of avoiding the abuse of these drugs.
4. Make recommendations for the company's marketing activities to ensure a favourable regulatory environment and achievement of her sales objectives.

## 1.6. THE SCOPE OF THE STUDY

The Study is a retrospective analysis covering 1993 - 1997, to determine and establish the impact of drug abuse, and regulatory controls arising from it on the marketing and sales activities of Benzodiazepine by Roche (Nigeria) Limited.

Thereafter sustainable and acceptable marketing strategies to sustain the sales of these products in the present business / regulatory environment shall be fashioned out for the company's operation in Nigeria.

In a free market economy like ours, Roche (Nigeria) Limited is not the only marketer / seller of Benzodiazepine; there are parallel marketers and generic importers of benzodiazepines. However only Roche (Nigeria) Limited produces and distributes Benzodiazepines in Nigeria.

In medical practice, Roche is strongly identified with Benzodiazepine and whenever Benzodiazepine is mentioned, sometimes, there is an enroueous association with Roche in all situations.

The study will involve review with relevant literatures as it regards the issue of drug abuse and Benzodiazepine abuse in particular. And also a review of the marketing activities in the pharmaceutical industry.

The company's operation will be assessed in relationship to the staff strength and sales performance over the period.

The regulatory activities of the two principal agencies over the period shall be reviewed. The interplay of these parameters and influence on the company's operations shall be analysed.

## 1.7. THE SIGNIFICANCE OF THE RESEARCH STUDY

Studies have shown that drug abuse is on the increase in Africa and other developing countries. The licit drug (alcohol, cigarette, Benzodiazepines) act as a “factory” to the use of illicit drugs. In turn the use of these illicit drugs (e.g. cannabis) increases the likelihood of the use of more dangerous drug, such as heroin, cocaine, amphetamine and solvent.

Drug abuse is associated with various adverse effects. These have been reported to be on the increase with rising prevalence of drug abuse.

For all these reasons regulatory agencies (NAFDAC and NDLEA) are set up by the Government to control (Production, distribution and consumption) of these drugs and ensure that only people who require these drugs (Licit drugs such as Benzodiazepine) genuinely get them.

*Lexotan is a very important product in the product portfolio of Roche (Nigeria) Limited and accounts consistently for over 15% of her sales revenue during the period of the study. Anything that impacts on the product negatively will impact on the company operations with attendant consequences on the work force and its larger Socio Economic implications.*

This study is therefore being embarked on to put in place appropriate marketing strategies to ensure licit use of lexotan, minimise impact of the regulatory controls and guarantee the sales of lexotan so as to ensure operational functionality of Roche (Nigeria) Limited.

For a company like Roche (Nigeria) Limited which is ranked 5th among the

pharmaceutical industries in Nigeria in 1997 and employing about 200 Nigerians, distortion in its activities will have significant impact in the industry and on the staff. Lexotan it is one of the main products absorbing the overhead cost of running Roche (Nigeria) Limited.

It has marketed the drug for the past 15 years, in Nigeria successfully and harassment of its distributive network as was the case in 1994 to 1996 has a tendency to send wrong signals to the market which have to be addressed in the interest of the growth and survival of the product and overall interest of the company.



## 1.8. LIMITATIONS OF THE STUDY

The study depended greatly on Historical data as sourced from the company. In this case, only Roche (Nigeria) Limited is involved in sale of lexotan in Nigeria. Though other companies are involved in the sales of Benzodiazepine in the market, the quantities involved are usually small and difficult to estimate due to the peculiarities of the market audit in Nigeria. Only Roche (Nigeria) Limited is involved in the marketing Benzodiazepins in large quantity in Nigeria.

Appropriate marketing of benzodiazepins will ensure that individuals not requiring the drugs are not unduly exposed to them with the attendant Socio-Economic consequences.

Achievement of the marketing objectives of Roche (Nigeria) Limited will ensure that her turnover and profit objectives are met so that it can maintain her workforce and make adequate payments of tax which will enhance the overall performance of the economy.

## 1.9 DEFINITION OF TERMS

**Abstinence Syndrome:** - The syndrome which occurs in drug-dependent people when the drug is withheld. It usually involves both physical and psychological manifestations, the nature of which varies with the drug on which dependence exists. It is also termed withdrawal reaction (q.v.) or withdrawal syndrome.

**Addiction:** - A term which is still widely used but which is variously understood and defined by physicians, sociologists and lawyers. It should be discarded for scientific purposes and replaced by the term dependence (q.v.) as defined by the World Health Organisation.

**Drug:** - Any substance which when taken into the living organism may modify one or more of its functions.

**Drug abuse:** - Persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice; cf. 'Misuse' (q.v.). The term abuse covers a wide range of different types of inappropriate use.

**Drug dependence:** - A state, psychic and sometimes also physical, which results from the interaction between a living organism and a drug, which is characterized by behavioural and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects and sometimes to avoid the discomfort of its absence. Tolerance may be present.

**Misuse:** - Medical or lay use of a drug for a disease state not considered to be appropriate by the majority. This has a close relationship with the term 'abuse' but the latter can probably best be considered in the more general context of 'affect modification' for personal gratification, whereas the former implies an attempted therapeutic effect, however misguided.

**Overuse:** - Excessive medical or lay use of a drug, in terms of length of therapy or severity of disorder treated, for diseases in which there is accepted evidence of therapeutic effect.

**Physical dependence:-** The drug, or one or more of its metabolites, has become necessary for the continued functioning of certain body processes. This creates in the dependent person on withdrawal of the drug true physically determined and clinically recognizable signs (the abstinence syndrome - q.v.). These are usually heavily overlaid with psychologically determined symptoms and often manifestations of the disease for which the drug was originally taken.

**Psychoactive substance:-** Any substance which influences mental processes.

**Psychological dependence:-** This involves purely emotional components with no physical signs on withdrawal. It runs at one end of the spectrum from the drug, through the emotional drives that lead the person to persist in its use, to the change in lifestyle, behaviour and personal involvement where the life pattern revolves around drug taking and the company of others similarly involved. At this extreme the drug use provides a total deviant career often

# **CHAPTER TWO**

## **LITERATURE REVIEW**

### **2.1 DRUG ABUSE AND CONTROL**

Drug abuse has of recent assumed a high economic and social relevance that various international concerns and specific plans to contain the menace is required.

Drug abuse is a persistent or sporadic excessive drug use in consistent with or unrelated to acceptable medical practice. The term abuse covers a wide range of different types of inappropriate use. The consequences of dependence, addiction, withdrawal symptoms etc. and associated socioeconomic costs of this problem is the main concern for regulation.

The term that is still in the widest use is addiction, but because of the differences that exist in its understanding, there is a growing tendency to use the word "dependence" and to adopt the World health Organisation (WHO) definition (1950). The basic terms are 'drug abuse' and 'drug dependence'. The WHO recommendation (1964) is that when drug dependence is being

discussed, the type should be specified because of their variations.

This subject will be better appreciated when we consider Marks remarks that “Humanity at large will never be likely to dispose of artificial paradises. Most men and women lead at the worst so painful, at the best so monotonous, poor and limited to the urge to escape, the longing to transcend themselves of only for a few moments, is and has always been one of the principal appetites for soul”.

Art and religion, carnival and saturation, dancing and listening to oratory, all have served in the HG Well phrase as a “doors in the wall”. And for private, everyday use, there have always been chemical intoxicants.

Most of the modifiers cannot now be taken except under doctors order or else illegally and at considerable risk. For unrestricted use, the west has permitted, only alcohol and tobacco. Even today the extent of alcohol consumption is being regulated in Europe for auto drivers.

There is scarcely any agent which can be taken into the body to which some individuals will not get a reaction, satisfactory or pleasurable to them, persuading them to the point of abuse (Eddy et al 1965).

For many, drugs that are over used are caffeine (tea/coffee), nicotine (tobacco) or alcohol (beer/wine etc) all socially acceptable and usually normal ingredient of everyday life of most communities. For a smaller group, the misuse concerns commonly prescribed medical substances of barbiturates and amphetamines. For an even a smaller group, there is the less socially acceptable or frankly unacceptable 'abuse' of specific substances such as solvents, morphine and related analgesics, cannabis or hallucinogens all taken to provide some form of positive pleasure or to relieve stress, anxiety, depression or pain.

One further term which can cause confusion in its usage is "pyschotropic". By basic definition, any substances that can lead to dependence must be psychoactive (it alter the mental processes.) Such substances and particularly those used for therapy of mental disorders, have been termed "psyhotropics" or "psychotropic substances".

However the United Nations Narcotic commission's definition reserves the term 'psychotropic' for a substances which leads to depedence (UN 1971). Control of psychoactive drugs at the international level rely mainly on the recognition of the responsibility which every country has for protecting the Health and Welfare of its citizen and their preparedness to develop and

implement measures to prevent the harmful consequences of indiscriminate drug use with consequent efforts on morale, families mental health, criminal activities etc.

At the national level, the protection of the citizens begin with the formulation and promulgation of appropriate domestic drug legislation which takes into account the obligation of states to use the control measures provided in such treaties as the minimum level of the national controls.

A series of international conventions and national drug laws govern the manufacture, importation, exportation, distribution and use of narcotics, psychotropic substances and other controlled drugs in Nigeria. The United Nation (UN) and World Health Organisation (WHO) are international organisations in the frontiers of this control.

The categorization of some psychotropic or psychoactive drugs into various schedules of the UN conventions on psychotropic substances (1961 & 1971) is based on the balance between their therapeutic usefulness and their abuse potential.

Today the most important conventions that govern the trade of psychotropic substances includes

1. The UN single convention on Narcotic drugs 1961 as amended by the protocol of 1971
2. The 1971 UN convention on psychotropic substances and
3. The 1988 UN convention against Illicit traffic in narcotic drugs and psychotropic substances.

These various conventions have also given rise to international institutions responsible for the administration of the conventions as follows:

- i. The United Nations commission on Narcotic Drugs (CND)
- ii. The International Narcotics Control Board (ICNB)
- iii. The United Nations International Drugs Control Programme (UNDCP)
- iv. The World Health Organisation (WHO)
- v. The Economic and Social Council of the United Nation (UNECOSOQ)
- vi. The general assembly of the United Nations.

At the national level, so crucial is the issue of regulation that the following legislations have been put in place for the purpose of control.

1. Poisons and pharmacy Act cap 152, Laws of Nigeria.
2. Food and Drugs decree 34 of 1974 (now cap 150 laws of the federation 1990)



3. Indian hemp decree of 1966 amended by Indian hemp decree of 1975.
4. Dangerous drug act cap 48 (now cap 91 of the law of the federation of 1990).
5. Decree 20 of 1984 -special tribunal (miscellaneous offences)  
Decree No.20 as amended by decree No. 31 of 1984 and further amended by decree No. 22 of 1988.
6. NDLEA decree No. 48 of 1989 (amended by decree No 3 of 1995)
7. Pharmacist council decree No. 91 of 1993
8. NAFDAC decree No 15 of 1993.

Such is the regulatory environment under which psychotropic drugs are marketed and sold locally and internationally.

## 2.2 BENZODIAZEPINES: USE AND ABUSE

By far the most widely prescribed psychotropic drugs are benzodiazepines which have largely replaced other tranquilisers because of their anxiety relieving efficiency coupled with a much wider safety margin. With this widespread use, it is inevitable that the question should be raised as to how far there is a medical justification for this amount of prescribing and how far abuse may account for it.

In benzodiazepines medication, the crucially important question is whether patients receiving tranquilisers are willing and able to comply with instructions and reduce their daily dose, in the course of four to six weeks by changing to intermittent medication when needed for relief of symptoms.

The excessive demand made on the human ability to modify emotional experience is one of the inevitable and distressing facts of existence against which nobody has a proof.

It is generally (medically) accepted fact today that the benzodiazepines with their anxiolytic or their antinociceptive characteristics (Wick) fulfil the therapeutic expectations of these patients and elicit the subjective experience

of drug action far more effectively than any other group of substances that is not based on the same mechanism of action.

Appropriate uses of tranquilisers is perfectly possible under the standard conditions of practice. The role of benzodiazepines in medicine was defined by Sternhack as a “highly active and yet very untoxic drugs, now turnout to be acting by enhancing a physiological and protective mechanism which is indispensable for normal functioning of the central nervous systems”. He concluded by saying “if we had to devise a useful type of neuro psychotropic drug today, based on the present knowledge of synaptic function and dysfunctions we would search for drugs like the benzodiazepines, if they did not exist”.

Brussnells justified the use of adequate tranquilizers to alleviate symptoms and remarked that benzodiazepines are extremely useful in developing countries because of their ease of management, safety, efficiency and effectiveness, but the risk of dependences or tolerance must be borne in mind. He recommended that non specialized persons can be trained to use benzodiazepines thus enabling a great proportion of all patients who are in need of this type of medication to be safely treated.

Various authors have reported the therapeutic usefulness of the benzodiazepines in several medical conditions ranging from its use in neurological disorders, epilepsy, insomnia, depression, drug withdrawal and anxiety.

In the words of Mark (1978) the extensive use of benzodiazepines is attributable to their efficiency as anxiolytics, hypnotics, muscle relaxants and anticonvulsant and their high level of safety. Compatible with most prescription and non-proprietary drugs, they are rarely fatal in either accidental or deliberate overdose.

Kaim reported that benzodiazepines may also be utilised as a therapeutic adjunct in getting chronic alcoholic patients involved in treatment. The short term use of anti anxiety and /or antidepressants agents can help anxious and depressed alcoholics to participate in comprehensive treatment programmes. The socioeconomic and psychological background of the individual patient may influence a specific type of programme as well as the out come of treatment.

### **2.2.1 BENZODIAZEPINES ABUSE**

As concluded by Harrer and Co, if benzodiazepines had been properly handled in the past, dependence would never have become a problem of practical importance.

According to Dr. YD Lapierre, just as the therapeutic uses of the benzodiazepines has grown dramatically, so too have the number of benzodiazepines available , thus raising important question regarding the benzodiazepines . In the analysis of risk benefit, John Marks concluded that associated risks of benzodiazepines medication are quite small. However, he cautioned physicians to avoid prescribing these agents to persons with known dependency problems, to caution patients to avoid their use with alcohol or other CNS depressants and to limit continuous medication to the months if possible, and patients should be withdrawn gradually from their medication to minimize abound efforts.

Lapierre remarked that benzodiazepines are far more beneficial than harmful if prescribed for the proper indications; if the choice of day is circumstances; and if the medication is tapered off rather than abruptly iscontinued.

Chronic intoxication can be serious impediment to driving. Some individuals have had highway accidents with personal injury and property damage (Macleod et al 1971).

Psychosocial implications of drug abuse include:

- Abstinence Syndrome
- Addiction
- Drug Dependence
- Drug Misuse
- Physical Dependence
- Rebound Phenomenon
- Psychological Dependence
- Tolerance and
- Withdrawal reaction

However 2 facts must be emphasised about chronic intoxication with benzodiazepines

\*Its incidence is low

\*With appropriate treatment, recovery can be complete.

Doctors can minimize the risk of dependence by restricting prescriptions to valid clinical indications, prescribing the lowest doses possible, by limiting refills and carefully monitoring patients, especially those with histories of

alcohol and or substance abuse. Furthermore, physicians should obviate the risk of moderate to severe withdrawal reactions by gradual discontinuation in anyone known or suspected to be a long term benzodiazepines user. Indeed dependency and withdrawal reactions have been reported with every benzodiazepines.

Historically, the primary responsibility of the pharmaceutical industry has been the research and development of safe and effective prescription medications. However it is now quite clear that the industry's responsibility extends beyond this to communication of appropriate and accurate information on these medications to physicians and other healthcare professionals. Nowhere is this more important than with the issue of the abuse potential of the benzodiazepines.

Any attempt to differentiate the abuse potential for members of the benzodiazepines class is one fraught with dangerous consequences.

Most authorities argue that because of the widespread therapeutic value of benzodiazepines nationally and internationally, any problems associated with their use cannot be successfully addressed on a regulatory basis. Information and education is clearly the most effective method of conveying

to both professional and non professional audience, the appropriate use of this significant class of medications.

Patients and the public at large have expressed an intense interest in learning more about prescription medications and the pharmaceutical industry should assume responsibility for providing the necessary information. By doing so, the industry can play a major role in improving the delivery of Healthcare.

The benzodiazepines are consumed by an estimated 15% of adult population each year and 3% each day in the US. At this high level of consumption, it is imperative to strive to know all that is possible about the ramifications of their uses.

The first marketed benzodiazepines chlordiazepoxide (Librium<sup>®</sup>) was introduced in 1960 followed by diazepam (Valium<sup>®</sup>) in 1963. The unfortunate aspect of this subject is the media involvement; trial by the media can never take the place of careful scientific evaluation of a psychotropic drug. The media cannot present information in detail. It titrates, dramatise and pulls fact out of context, it is unfortunate but this is so.



Various authors have concluded that documented cases of dependence on the benzodiazepines are rare in relation to their extremely widespread use. However their liability to abuse exist. The danger of such dependence can be largely avoided by careful prescribing habits.

Indeed, until subsequent evaluation of its therapeutic applications, benzodiazepines were originally used by or under the immediate direction of psychiatrists. Now the majority use is by general practitioners and psychiatrists mainly see the therapeutic failures. In consequence, new problem have emerged. Rarely, pure abuse of benzodiazepines is reported. As Smith (1983 & 1985) stressed, narcotic are drugs of primary dependence but benzodiazepines are not. WHO (1982) accepted that very few persons use benzodiazepines as the primary drug of abuse.

### **2.2.2 BENZODIAZEPINES AND THE REGULATORY ENVIRONMENT**

Under the UN convention of 1971, drugs are listed in schedule I - IV based on their therapeutic evaluation and abuse potential. The benzodiazepines are listed in schedule IV which is indicative that they possess a very high therapeutic benefits out weighing their abuse potential.

The benzodiazepines are a group of drugs used for the treatment of the following conditions

- Anxiety
- Convulsion
- Muscle stiffness
- Insomnia and
- Other related disorders.

Over 30 different benzodiazepines are available world over and more that 15 of them are from Roche.

For marketing administration, they have been classed as “Central Numerous System (CNS) drugs”. As a therapeutic group it generated the highest sale for F. Hoffman -Roche Ltd amounting to 23% of her total 1995 Pharmaceutical turnover. (World Wide Sales)

For Roche (Nigeria) Limited, it is the second ranking after antimalarial, in sales contribution. Because of its schedule status, the benzodiazepines are subject to some levels of control.

Under article 19 of the 1960 convention, every state party to the conventions has an obligation to provide an annual estimate of the actual quantity of narcotic drugs required for use in its territory during the following calendar year. Such estimates are now being provided on a voluntary basis in respect of requirements of psychotropic substances.

The estimates are very important for control purposes but can only be reliable if compiled from systematically detailed information and data on therapeutic application of the drugs obtained from hospitals, clinics, pharmacies, research institutions as the pharmaceutical industry.

The controls on benzodiazepines are both at national and international level. Such control have necessitated additional planning techniques relevant to the importation, manufacturing and sales of the psychotropics.

The issue of drug abuse and indeed benzodiazepines abuse in Nigeria has been extensively studied and various submission made at an international

workshop in 1989 and result of various community studies were discussed.

1. Drug group directly dispensed in Nigeria pharmacies showing number of medications dispensed, Obadeyi et al

<b>Drug group dispensed</b>	<b>%</b>
Analgesic/antipyretic	18
Antibiotic	15
Antimalarial	9
Multivitamins	8
Antihistamine	4
Antispasmodic/GI	3
Benzodiazepines	3
Antiparasitic	3
Expectorant/cough	3
Antidiarrhoea	3
Antifungal	3
Other	31
Total	100

Benzodiazepines are rated as the 7th drug of abuse in Nigeria.

- ii. Selected drugs in treatment.

<b>Drug Group</b>	<b>Complaint treated</b>	<b>Number</b>
Traquilizer	No complain given	134
	Sleep disturbance	108
	Pain	87
	Anxiety	31
	Respiratory dis	29
	Other	66

This is indicative of high use of benzodiazepines without proper diagnosis

- iii. Proportion of selected drug request by name:

	% Represented by name	% Chosen by Pharm
All request	66	34
Antibiotics	57	43
Multivitamin/Vitamins	42	58
Tranquilliser	66	33

This is indicative of a high specificity in the request for benzodiazepines.

- iv. In a related result by Odutola et al in the community practice, the following was obtained in study of various preparations, per store

Pharmacologic group	No. of preparations. store
Antibiotic	9
Antimalarial	16
Sedatives/tranquilisers	6
Vitamins/Tonic	32

This is indicative of a very low range of benzodiazepines in shop

## CHAPTER 3

### **HISTORICAL BACKGROUND OF ROCHE (NIGERIA) LIMITED.**

#### **3.1 ROCHE (NIGERIA) LIMITED AND F. HOFFMANN LA - ROCHE LTD BASLE**

Roche (Nigeria) Limited is a limited liability company established under the companies Act 1964 and was owned 40% by F. Hoffman La - Roche Ltd, Basle Switzerland and 60% by private Nigerian citizens. The company was established in Nigeria in 1976, making the existence in Nigeria 20 years.

In April 1996, through a conversion of redeemable preference shares and part of their long term loan, the share holding of the Roche group was increased to 60%, while the Nigerian interest reduced to 40%.

Thus Roche (Nigeria) Limited is a subsidiary of F. Hoffman La - Roche Basle. The company is engaged in the manufacturing, marketing and distribution of:

- Pharmaceuticals
- Bulk Vitamins and
- Fine chemicals / flavours

The history of the company dates back to the 1890s. On March 31 1894, twenty six year old Fritz Hoffman (a textile/dyestuff merchant) and Max Carl Traub, a Munich pharmacist founded a limited partnership, Hoffman Traub and Co in Basel, to manufacture and sell pharmaceutical and chemical preparations and products. Two and half years later or October 1 1896, the partnership broke down and it was registered as F. Hoffman La - Roche and Co (the origin of the sort term 'Roche' by which the company is known worldwide today).

At the end of 1894, a whirl wind courtship by Fritz had resulted in his engagement to Adele La Roche and they got married in 1895.

The company went for its first international operation with an agency in Paris in 1896. It started operation in Milan, Italy in 1897 and opened a plant in Grenzach Germany in 1899. The Roche network today is consisted of more than 100 affiliates/subsidiaries worldwide with a staff strength numbering over 60,000 people.

Other affiliates and subsidiaries include those in USA, Germany, Norway, Brazil, Japan, Peru, Argentina, South Africa, Israel, Spain, Canada to mention but a few.

### 3.1.1 THE VALIUM BOOM OF THE 1950S

In the 1950s the success other companies were having with mild tranquilisers encouraged Roche to return to its traditional field of research and eventually lead to the development of benzodiazepines tranquilisers. The 10 years triumph (1950s - 1960s) of Librium<sup>®</sup>, Valium<sup>®</sup> and other benzodiazepines derivatives made Roche the world's leading pharmaceutical corporation in terms of sales. Hence the importance attached to the benzodiazepines in the portfolio of the company's products.

After such a success with the benzodiazepines and the declining fortunes of the company, by 1978, the company inaugurated a turn around, and resources were concentrated on core pharmaceuticals and vitamins businesses and the closely related fields of fragrances, flavours and diagnostics.

Therapeutic areas for which Roche had been working for declares produced successful new drugs such as

Anti biotic	-Rocephin
Anti depressant	-Aurorix and
Biotechnology products	-Roferon-A, Hivid, Invirase etc.



### 3.2 OBJECTIVES OF ROCHE NIGERIA LIMITED

The objectives of Roche Nigeria Limited is as contained in the Corporate principle as outlined below.

“Our aim is to discover, produce, and market goods, and provide services which meet human and animal health needs in the areas of prevention, diagnosis, treatment and general well being. We will also actively pursue other business opportunities provided they allow us to capitalise on our human, technological and financial resources.

#### Service to customers:

A prime objective of our company is to meet our customers’ needs for quality products and services. This implies identifying and solving their problems, intensifying contacts with them, listening to what they say and anticipating the future needs of the market.

#### Respect for individual:

We believe that the sales of our company depends on the combined talents and performance of dedicated people. For this reason we want:

- Everyone in the organisation to respect each others rights and dignity.

- To help our people to develop their talents and to make optimal use of their abilities and potentials.
- To provide recognition based on performance and contribution to Roche success.
- To encourage information sharing and open dialogue.

**Leadership:**

We want to meet high standards of performance in all our activities. We are committed to selecting, developing and promoting managers with self-drive and empathy who

- Combine professional competence with a leadership struggle that motivates people to high performance.
- Have an open mind, understand the needs of the company and have the courage to question decision and actions.

**Obligation to stockholders and employees:**

In order to maintain our commitment to research, ensure our growth and independence, provide employment opportunities, cover risks and pay an attractive return on invested capital, we aim to achieve above average profitability in our industry.

### Obligation to Society:

We want to maintain high ethical standards in our business dealings and in our efforts to protect the environment. We will also maintain standards in adhering to local, national and international laws, in cooperating with authorities and in communicating with the public.

### Open to change:

We want to be innovative and see change as an opportunity. Being active in high technology fields, we must recognise new trends at a very early stage and be open to unconventional ideas. We see complacency as a threat. It is therefore our policy to encourage everywhere in the company, the curiosity needed to be open to the world and to welcome change”.

The driver of her business is the pharmaceutical division whose aims are clearly stated as follows:

- To achieve leadership through outstanding performance on all that they do by superior **innovation, speed and growth** with values of
  - \* A performance culture which is passionate about setting ambitious goals and rewarding achievement.

- \* Global teamwork to build competitive advantage
- \* A drive to change by taking informed risk and by courageous leadership
- \* A sense of urgency and empowerment at all levels of the organisation.
- \* Clear transparent two-way communication.

### **3.3 ORGANISATIONAL STRUCTURE**

The Organisational structure of the company is attached (Appendix B). The Pharmaceuticals Division is headed by the Pharmaceuticals Manager. The detailed organogram of the division is also attached (Appendix C).

### **3.4 FUNCTIONAL OPERATIONS OF ROCHE (NIGERIA)LIMITED**

The company is run by a management team referred to as the Senior Management Committee and a Senior Management meeting (SMM) is held on a monthly basis to appraise the company operations. SMM members are made of Divisional heads as highlighted in the organogram and the meeting is chaired by the Managing Director, who is the Chief Executive.

- The Managing Directors Office is responsible for the overall administration of the company.
  
- The Pharma Technical Operations and Manufacturing division is responsible for the procurement of raw materials, production and packaging of drugs and ware housing requirements. It is also in-charge of logistics (importation and local distribution).
  
- The workshop is responsible for the maintenance work of the company infrastructures (including vehicles and the production plant).
  
- The Human resources and Public relations division is responsible

for personal matters, public relations, welfare issues and canteen services.

- The finance division is responsible for the financial planning and controlling of the company operations.
- The special duties unit is responsible for procurement services as required by the divisions as well other special assignments that may be requested from time-to-time (especially with various agencies of Government).
- The Pharmaceuticals Divisions is the lifewire of the company and it is responsible for the marketing and sales of imported timmled products and local produced drugs by the plant

### 3.4.1 SALES

The company is engaged in profitable business as indicated below in the growth, turnover, profit and dividend in the last 5 years.

	1993	1994	1995	1996	1997
<b>Turnover (=N= mio)</b>	268.50	424.50	571.10	718.50	714.50
<b>Profit after tax</b>	15.15	26.04	49.54	37.25	(53.61)
<b>Dividend</b>	6.0	12.0	20.0	13.40	8.9

### 3.4.2 PERSONNEL

As at 1997, the company is composed of a workforce of 163 persons made up as follows: The distribution over the five year period is as follows:

	1993	1994	1995	1996	1997
Administration	57	54	62	64	59
Sales & Marketing	40	48	58	63	55
Distribution & Ware Housing	26	25	23	20	9
Production	25	27	29	28	34
Engineering	9	11	11	11	6
<b>Total</b>	<b>157</b>	<b>165</b>	<b>183</b>	<b>186</b>	<b>163</b>

### 3.4.3 PRODUCTS

In terms of sales and marketing and for the purpose of the subject matter, the most important/relevant department is the pharmaceutical division which accounts for over 80% of the company total turnover and markets the range of products under discussion (the Benzodiazepines). The major products of the division are classified as follows:

- Antimalarials - Fansidar, fansimef and lariam
- Antibiotics - Rocéphim and Bactrim
- Biotech products - Roferon-A
- Benzodiazepines - Valium, Mogadon, Rohypnol, Lexotan and Dormicum.
- Analgesics - Saridon-P
- Antidepressants - Aurorix

The antimalarials and the Benzodiazepines account for over 70% of the annual turnover of the division. In 1997, Roche is ranked 5th amongst the pharmaceutical companies operating in Nigeria and it is situated in the Ikeja Industrial area of Dopemu, Lagos State.

### **3.6 MARKETING ACTIVITIES IN THE COMPANY**

The marketing activities in the company is a responsibility of the Pharmaceuticals Division. The products marketed by Pharmaceutical Industry are broadly classified as:

- Over the counter (OTC) drugs - which are drugs that can be sold at patient's request or discretion of operatives of pharmacy retail outlets.
- Ethical drugs - these are drugs that can only be dispensed on the order of a registered Doctor's prescription.

The companies marketing activities are structured such that there is a unit in-charge of Ethical (Rx) marketing and OTC marketing. All plans developed by these units are implemented by the sales force/field force staff which is another subunit of the pharmaceuticals division. It is directly responsible for the achievement of sales target through the implementation of marketing plans.



Different managers are in charge of the different units and subunits of the pharma division issues that bother on regulatory activities and the company liaison with relevant regulatory agencies viz PCN (Pharmacists Council of Nigeria), NAFDAC (National Agency for Food and Drugs Administration and Control) and NDLEA (National Drug Law Enforcement Agency) are entrusted in the hands of a manager (Appendix C refers).

### **3.7 GENERAL MARKETING PROBLEMS OF ROCHE**

The marketing problems, encountered by the company include:

- Insufficient data necessary for marketing planning.
- Information in the pharmaceutical industry is highly deregulated and syndication which is expected to generate useful/ consolidated data is not subscribed to by some key players in the market. In addition due to the 'porous' ports of entry to Nigeria a lot of imports are not regulated or documented.
- The interference of regulatory agencies on marketing activities. A lot of the company operations are highly dependent on approvals of the regulatory agencies; delays can sometimes cause great distress to the marketing operations. For example any outlet where it is intended to store drugs (warehousing) must be registered and approved by the

PCN and NAFDAC.

Any new drug, formulation or pack that will be introduced must be approved by NAFDAC. Most (or all the times). Progress in marketing activities is highly dependent on regulatory approvals. Unfortunately, these agencies have the limitation in terms of manpower and other resources which invariably delays approval process.

As for psychotropics, the process of importation (raw materials or finished products), manufacture and distribution is wholly regulated and controlled by NAFDAC.

In Nigeria, legislation and guideline cover the following areas of psychotropic trade

- \* Importation of psychotropic substances and other controlled drugs.
- \* Clearance of imported psychotropic substance from the port on importation.

Usually, an application is required for the importation to be submitted by the importing organisation.

- \* Name of Bulk narcotics / psychotropic substances to be imported
- \* Quantity to be imported
- \* Name and formula of preparation to be manufactured
- \* Name and address of manufacturer /exporter
- \* Name and signature of Superintendent Pharmacist

With an approval of the director general NAFDAC, a successful applicant is issued with authorisation stating

The name of the drug

\*The international non proprietary name if any

\*The quantity

\*The name and address of importer

\*The period within which the import is to be effected (usually within six months)

Upon receipt of consignment, the importer will inform the narcotic control branch of NAFDAC with a letter accompanied with photocopies of.

\*Export licence accompanying the consignment

\*The certificate of analysis

This is to maintain a record necessary for submission to ICNB view.

Subsequently, the manufacturer/importer (such as Roche) must maintain record of the use and disposal so that they can be inspected from time to time.

On a quarterly basis, reports/returns are submitted to NAFDAC on their utilization and disposal.

### **3.7 PROSPECTS OF ROCHE (NIGERIA) LIMITED**

Despite the Environmental Economic Constraints, there is a future for Roche Nigeria Limited. It was ranked 2nd among the 10 top Pharmaceutical companies in Nigeria in 1994, 4th in 1995, 6th in 1996, and 3rd in 1998. (Appendix A).

There has been progressive increase in sales turnover from 1993-1997.

Two class of products account for about 70% of the sales turnover. They are FANSIDAR ranges and benzodiazepines.

The future for the company is therefore to consolidate on these two products and expand to other therapeutic areas such as has been done

## **CHAPTER FOUR**

### **4.1 THE METHODOLOGY OF THE STUDY**

#### **TYPE OF DATA**

Primary data was collected using the historical research method. This involves retrieving relevant data regarding the company operation during the study period and their interpretation. Primary sources of data were provided by the source documents available in the company. Key officers of the company (Roche Nigeria Limited), NAFDAC and NDLEA were interviewed on aspects of drug abuse and control.

Historical search were made into the company's book for the following paramates during the study period.

- \*Sales performance (Value) for the company.

- \*Sales performance (Units & Value) for lexotan.

- \*Assesment of lexotan in relation to the entire product portfolio.

- \*Regulatory intervention during the period.

#### **DATA ANALYSIS .**

Descriptives statistics is used in interpreting the results and also involving the use of graphs.

# CHAPTER FIVE

## DATA PRESENTATION AND ANALYSIS

### 5.1 COMPANY SALES TURNOVER VS LEXOTAN SALES

The company recorded consistent growth in sales turnover and in the pharmaceutical operation during the period, 1993 (N163 Million), 1994 (N301 million), 1995 (N406 million), 1996 (N533 million) and 1997 (N509 million). Correspondingly, the Benzodiazepines contributed greatly to the growth recorded over the years 1993(18.08%), 1994 (23.80%) 1995 (22.65%), 1996 (22.54%) and 1997 (26.62%). Lexotan is the focus of analysis representing the group because it is the singular greatest contributor to sales out of all the benzodiazepines and the most popular in the medical field. Its singular contribution to sales over the period are 1993 (13.24%), 1994 (18.33%) 1995 (17.62%), 1996 (15.24%) and 1997 (15.76). It has remained consistently the No. 2 product in the company's portfolio as regard contribution to turnover except in 1997.

The trend to increasing sales over the period may be attributable to the impact of inflation as this period witnessed monetary policy changes that gave rise to heavy devaluation of the Naira especially 1993 - 1995. There were repeated price increases over the period that tended to increase the revenue generated with smaller units of drugs.

The total pharماسales increased over the period of 1993 to 1997 in Nigeria. The benzodiazepines/lexotan sales also increased during the period. The Lexotan contribution remained stable as a proportion of the total sales of the company from the period 1993 to 1997 (Table, Figures 1, 2 and 3, page 71,72, 73 and 74 refers).

The influence of price increase is palpable from the periods 1993/1994 (Turnover of N163/302 Million), 1994/1995 (N302/406 Million) and 1995/1996 (N406/533 million). The stability /decline in sales turnover 1996/1997 (N532/509 million) is due to the stability in the Exchange rate of the Naira and inability of the market to tolerate any excuse for price increase. This is coupled with stock out for LEXOTAN® for a quarter during the year.

## **5.2 LEXOTAN SALES IN VALUE**

Similar to the increased sales in company turnover during the period (1993-1997). Lexotan recorded increased sales 1993/1994 (N22/55million) 1994/1995 (N55/72 million), 1995/1996 (N72/81 million) and this stabilised in 1996/1997 (N81/80 million). As was the case with increased turnover 1993-1996, the main factor here is inflation driven price increases and as the environment could not tolerate price increases in 1999 sales revenue remained stable during the period (1996-1997). (Figure 2 page 73 refers)

## **5.3 LEXOTAN SALES IN UNIT**

The unit sales of lexotan increased tremendously from 1993 to 1994 (444.187 vs 700.474). This period (1993 and 1994) attracted very high promotional activities (seminars and detailing) to the medical community and the brand became very popular then. Thus, the increased sales in 1994 over 1993 can be interpreted as real growth (N55 million vs N22million). This period was the beginning of the Foreign Exchange devaluation and the impact was not very great on pricing. The success of the 1993/1994 and increased popularity of lexotan increased the curiosity and interest of the regulatory agencies (NAFDAC and NDLEA) in the brand. The period of



respect to individual unit packs of Lexotan. Four pack sizes are accountable for Lexotan sales.

Lexotan tablets	1.5mg x 30
“	“ 3mg x 30
“	“ 1.5mg x 500
“	“ 3mg x 500

#### 5.4 LEXOTAN SALES IN TABLETS

Similar to what was obtained for the units the peak sales was in 1994 as follows:

1.5mg - 10.6 million tablets

3mg - 13.9 million tablets.

The results in attributable to increased promotional activities.

There was a steady decline from 1994 to 1997.

\* 1.5mg - 10.6 million (1994) tablets to 5.9 million (1997) tablets and

\* 3mg - 13.9 million (1994) tablets to 8.3 million (1997) tablets

(Figure 5 page 76 refers)

This is attributable to the impact of regulatory controls and inflation as previously explained. The regulatory controls at international

level also affected the importation of the raw materials. This situation was responsible for the stock out for almost 3 months in 1997 this is partly responsible for the decline in sales observed during the year.

#### **5.5 REGULATORY INTERVENTION**

Routinely, NAFADAC is vested with power to inspect pharmaceutical premises to ensure that they are registered by the pharmacists council of Nigeria and hence entitled to trade in Benzodiazepines. In addition they are to inspect relevant books as prescribed by law to be maintained while selling these drugs. The penalty for default is the sealing of the shop (s) concerned and prosecution of the owners. This they have consistently carried out and stepped up in 1995 when the international pressure on Nigeria increased as regards the level of drug trafficking (in Nigeria).

For a similar reason (international blacklisting of Nigeria) the NDLEA stepped up its control. Unfortunately instead of concentrating on hard and Illicit drugs, some of the operatives exploited their decree to harass pharmaceutical wholesalers and retailers.

During the year 1995/1996, record has it that not less than 25 registered pharmacy wholesalers and retailers were arrested by NDLEA. As fraudulent as the arrests were in many cases, fears were sent down to the distributive channels. Most people preferred to stay clear of these drugs rather than have the troubles and with NDLEA authority. That is responsible for the decline in units and tablets sold as the full influence of these activities was felt in 1995. Subsequently many more retailers and wholesales have been disengaging from stocking these drugs and this certainly is responsible for the declining unit sales, in addition to the price increase during the period.

The regulatory interventions that can impact on sales are as follows:

- International Narcotic inspection leads to delayed shipment (lead time / inventory planning become more complex), such as the 1997 experience for Roche.
- Inspection in Nigeria by NAFDAC - normally permits are required from NAFDAC for the importation of specified quantities. Once the drugs arrive, the agency is contacted again for another permit to enable clearing.

These lead to delay in receipt of raw materials and finished goods sometimes leading to production delays and stock outs / loss of sales. Arrest and detention of some wholesalers involved in distributing the drugs by NAFDAC and NDLEA operatives send wrong signal to the distributive channels. With increased drug abuse, these measures are applied more strictly.

## **5.6 THE FINDINGS OF THE STUDY**

From the results, sales turnover for Roche Nigeria Limited increased consistently from 1993-1996 and declined in 1997 (1993 - N163million, 1994 - N301 million, 1995 N 406 million, 1996 - N533 million, 1997 - N509 million).

The value sales for Lexotan increased consistently during the period 1993 - 1996 and stabilised in 1997 (1993 - N22 million, 1994 - N55 million, 1995 - N72million, 1996 - N81million, 1997 - N80 million). Inflation was of great influence in the turnover picture of 1995 and 1996. Regulatory controls by NAFDAC and NDLEA influenced Lexotan sales in 1995, 1996 and 1997.

## 5.7 GENERAL DISCUSSION ON THE FINDINGS

In the pharmaceutical industry like others, the marketing activities generate sales on sales for according to Levitt, selling is preoccupied with the need to convert products to cash and marketing with the idea of satisfying the needs of the customer by means of the product and the whole cluster of things associated with creating, delivering and finally consuming it.

The real growth in Lexotan sales from 1993 to 1994 as typified by the growth in units sales is a direct reflection of implementation of marketing activities. Specific programmes were designed and implemented in 1993/1994.

In assessing the overall performance, it was evident that while there was steady increase in sales value in 1994 to 1996, this results were prompted only by price increase driven by inflation. In unit terms Lexotan sales was steadily declining. This is greatly accounted for by the immense regulatory pressure on the distributive channel during the period.

It has therefore become very useful to look more into issues anagement in the successful marketing of Benzodiazepines/Lexotan.

**NL ANNUAL TURNOVER FIGURES (1993 - 1997)  
BY PRODUCTS**

PRODUCT	1993		1994		1995		1996		1997	
	Sales (€M)	% Contribution	Sales (€M)	% Contribution	Sales (€M)	% Contribution	Sales (€M)	% Contribution	Sales (€M)	% Contribution
1 FANSIDAR	95,988,692.00	58.94	120,198,348.00	39.87	183,229,870.00	45.11	203,444,134.00	38.20	161,779,384.00	31.78
2 SUPRADYN	4,221,330.00	2.59	36,721,687.00	12.18	41,383,756.00	10.19	68,575,083.00	12.88	87,901,222.00	17.27
3 LEVOTAN*	21,603,593.00	13.24	55,272,789.00	18.33	71,585,291.00	17.62	81,199,791.00	15.24	80,218,579.00	15.76
4 VALIUM*	3,973,933.00	2.44	7,512,536.00	2.49	7,205,988.00	1.77	22,115,001.00	4.15	39,585,729.00	7.78
5 ROCEPHIN	4,262,422.00	2.61	8,444,000.00	2.80	11,861,687.00	2.92	19,414,359.00	3.65	21,812,192.00	4.29
6 SARDON P	17,497,408.00	10.72	31,157,269.00	10.33	23,971,973.00	5.90	33,227,720.00	6.24	19,467,920.00	3.83
7 FANSIMEF	0.00	0.00	5,480,114.00	1.82	6,957,875.00	1.71	12,438,094.00	2.34	14,641,354.00	2.88
8 POL YCROL	0.00	0.00	0.00	0.00	0.00	0.00	327,440.00	0.06	13,312,623.00	2.62
9 BACTRIM	5,404,250.00	3.31	12,091,249.00	4.01	18,655,966.00	4.64	37,273,679.00	7.00	10,721,470.00	2.11
10 INAVRASE	0.00	0.00	0.00	0.00	0.00	0.00	125,000.00	0.02	10,425,792.00	2.05
11 MOGADON*	2,849,809.00	1.75	5,189,431.00	1.72	7,465,333.00	1.84	12,614,583.00	2.37	9,686,109.00	1.90
12 ROMILAR	2,305,593.00	1.41	3,408,523.00	1.13	4,124,027.00	1.02	6,477,695.00	1.22	5,559,547.00	1.09
13 HVID	0.00	0.00	0.00	0.00	0.00	0.00	95,000.00	0.02	4,280,092.00	0.84
14 NAXEN	0.00	0.00	0.00	0.00	0.00	0.00	1,720,671.00	0.32	3,770,264.00	0.74
15 ROHYNOL*	1,096,210.00	0.65	2,668,205.00	0.89	4,107,820.00	1.01	2,581,136.00	0.48	3,759,379.00	0.74
16 ROFERON -A	0.00	0.00	85,403.00	0.03	2,551,699.00	0.63	6,180,830.00	1.16	3,527,705.00	0.69
17 AURORIX	0.00	0.00	0.00	0.00	836,220.00	0.21	4,154,896.00	0.78	3,155,087.00	0.62
18 ROVINGON	200,594.00	0.12	1,329,775.00	0.44	4,839,150.00	1.19	3,071,974.00	0.58	2,927,247.00	0.58
19 AROVIT	911,347.00	0.56	2,842,990.00	0.94	4,087,615.00	1.01	4,338,993.00	0.81	2,524,724.00	0.50
20 CAL C VITA	302,555.00	0.19	1,770,048.00	0.59	2,994,416.00	0.74	2,690,325.00	0.50	2,258,938.00	0.44
21 DORNICUM*	0.00	0.00	1,154,126.00	0.36	1,676,696.00	0.41	1,599,770.00	0.30	2,229,058.00	0.44
22 REDOXON	838,066.00	0.51	1,822,824.00	0.60	2,327,807.00	0.57	3,675,822.00	0.69	2,180,987.00	0.43
23 LARJAM	0.00	0.00	1,789,820.00	0.59	1,400,093.00	0.34	1,337,514.00	0.25	1,168,216.00	0.23
24 EBHYNAL	1,148,033.00	0.70	1,340,795.00	0.44	3,944,489.00	0.97	2,836,975.00	0.53	935,421.00	0.18
25 PROSTIGMIN	154,561.00	0.09	312,178.00	0.10	326,680.00	0.08	636,314.00	0.12	788,792.00	0.16
26 BEPANTHEN	178,828.00	0.11	381,004.00	0.13	165,261.00	0.04	378,336.00	0.07	259,584.00	0.05
27 BECOZYM	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
28 IMADYL	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
29 FLUORO URACIL	141,713.00	0.09	120,599.00	0.04	154,968.00	0.04	81,986.00	0.02	0.00	0.00
30 KONAKION	54,749.00	0.03	131,165.00	0.04	149,688.00	0.04	0.00	0.00	0.00	0.00
31 LIBRIUM	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
32 LITRISON	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
33 MADOPAR	57,215.00	0.04	265,547.00	0.09	0.00	0.00	0.00	0.00	0.00	0.00
34 SANATOGEN	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>TOTAL</b>	<b>163,164,811.00</b>	<b>100.00</b>	<b>301,490,325.00</b>	<b>100.00</b>	<b>406,204,367.00</b>	<b>100.00</b>	<b>533,564,121.00</b>	<b>100.00</b>	<b>508,867,405.00</b>	<b>100.00</b>

TOTAL % OF \* (BENZOS) =

18.08%

23.81%

22.65%

22.54%

26.62%

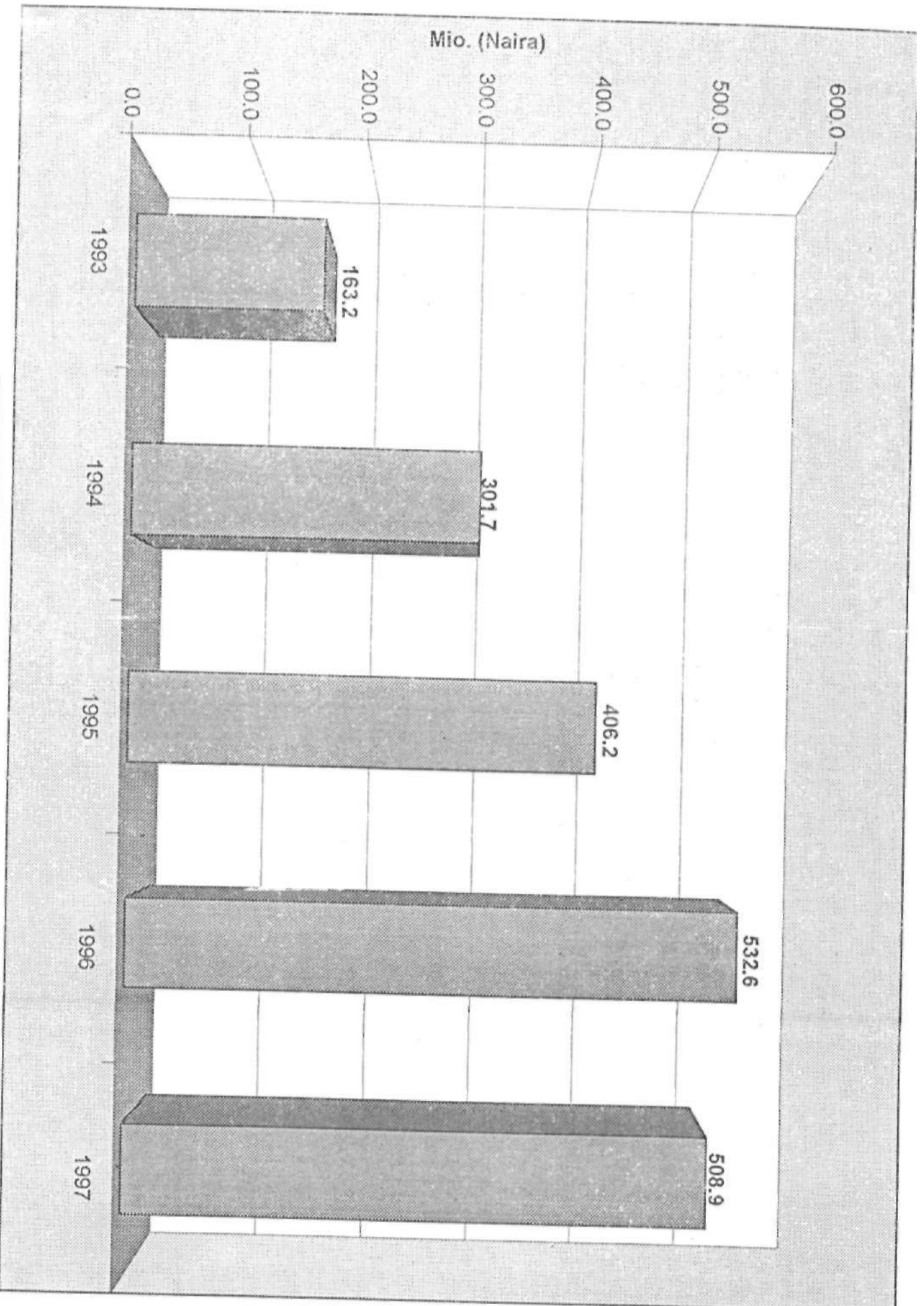


Figure 1: PHARMA TURNOVER 1993 - 1997

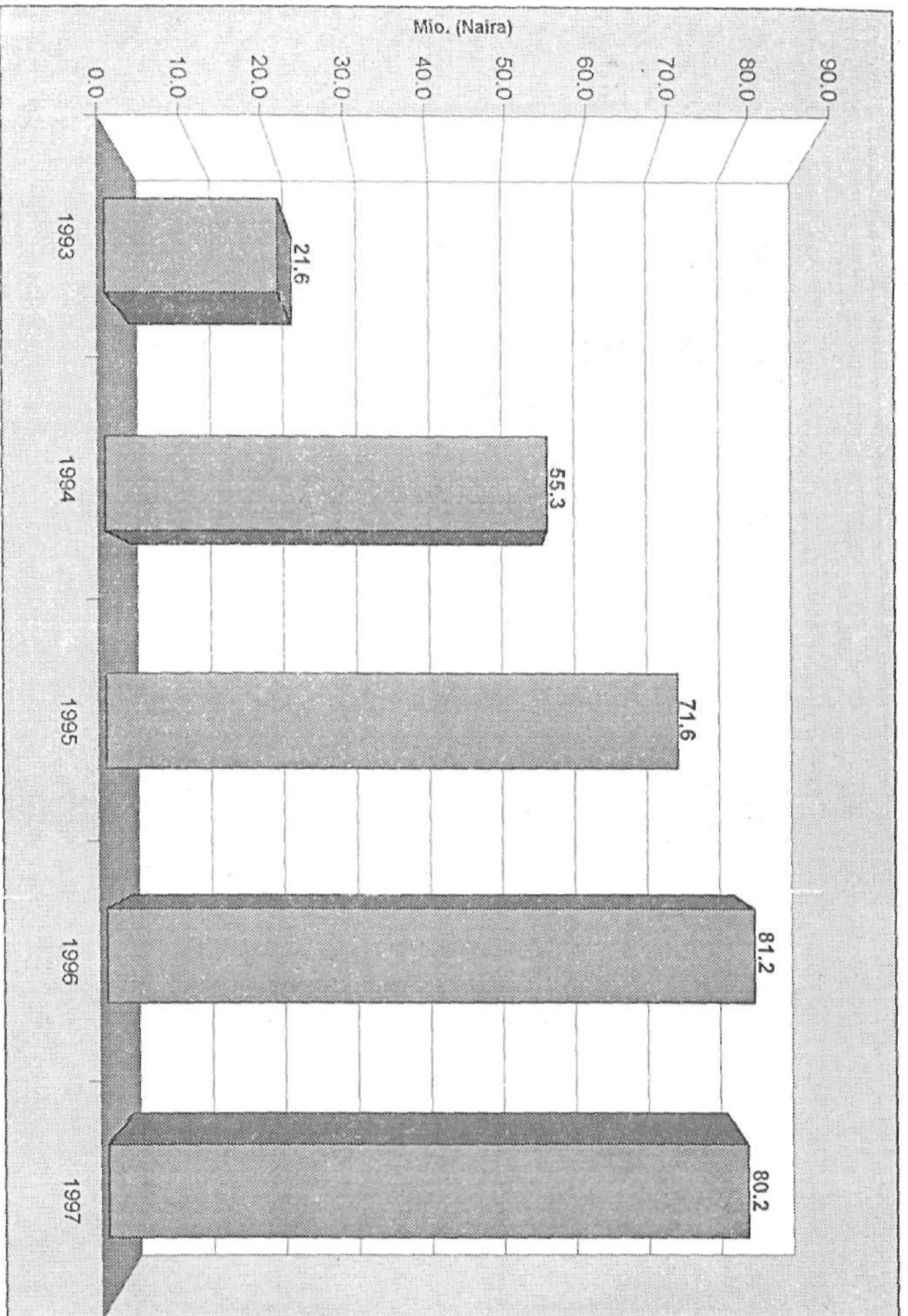


Figure 2:

LEXOTAN SALES IN VALUES (=N=) (1993 - 1997)



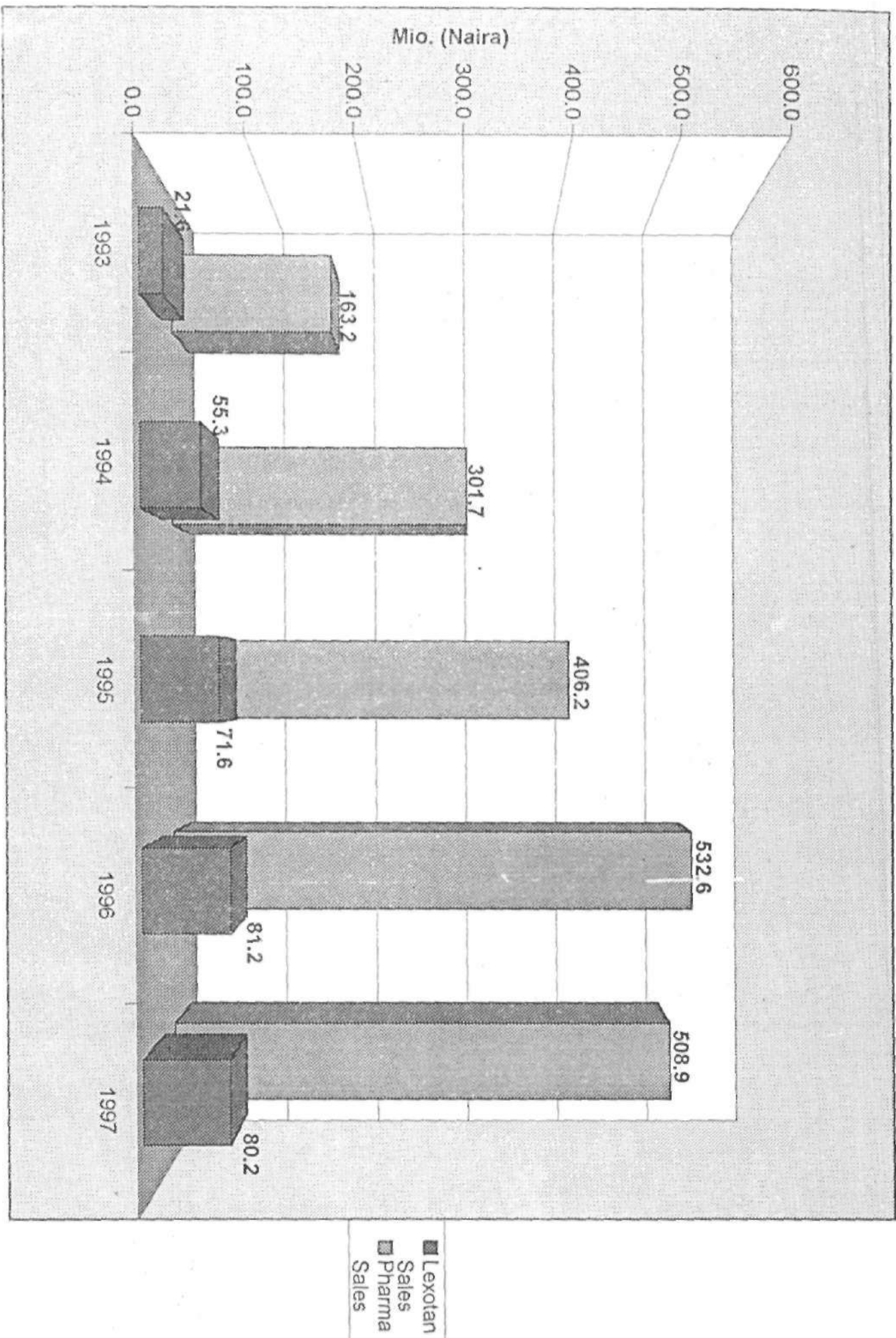


Figure 3: PHARMA TURNOVER VS. LEXOTAN SALES

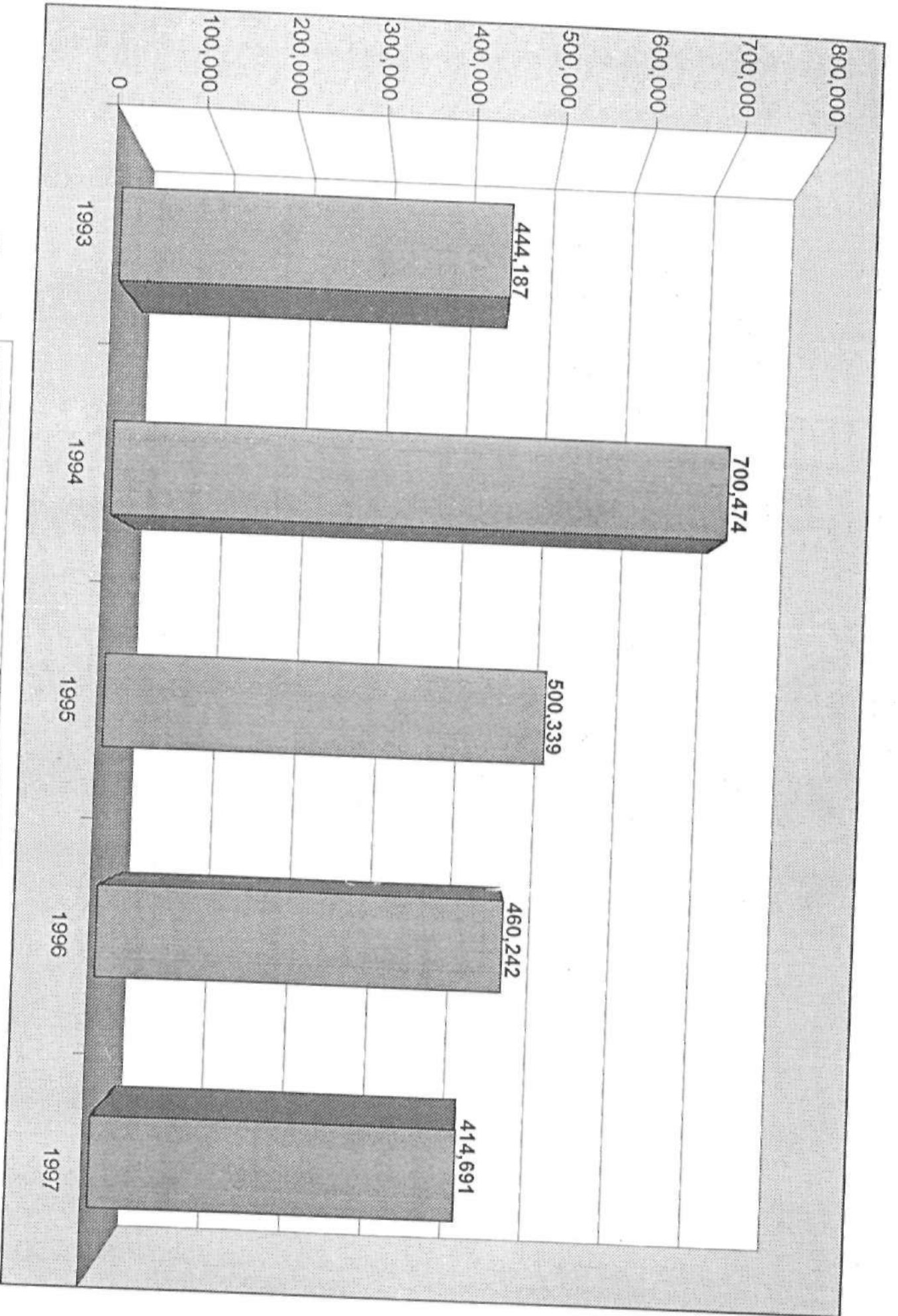


Figure 4: LEXOTAN: TOTAL UNITS SOLD (1993 - 1997)

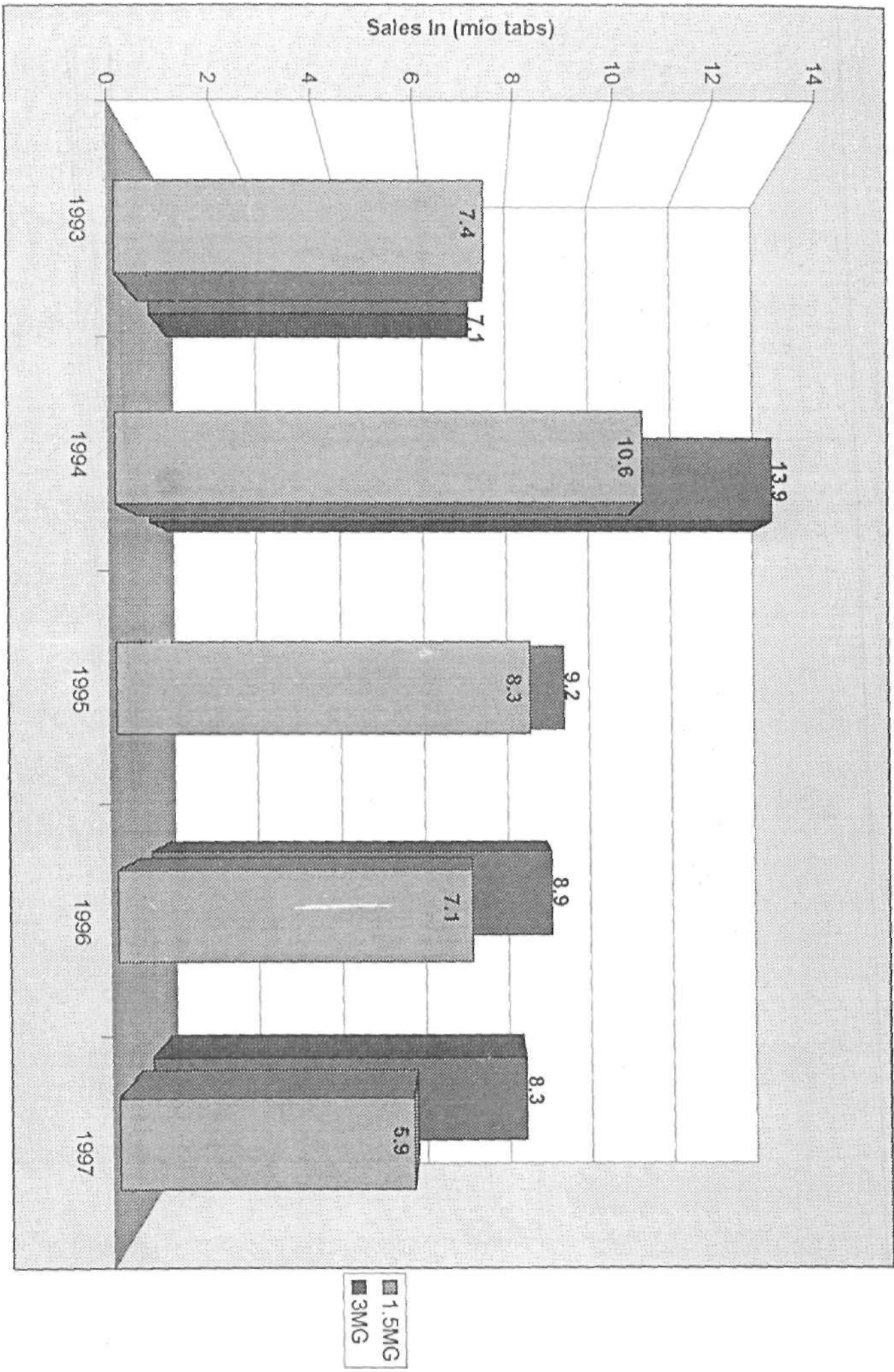


Figure 5:

LEXOTAN SALES (MIO TABS) (1993 - 1997)

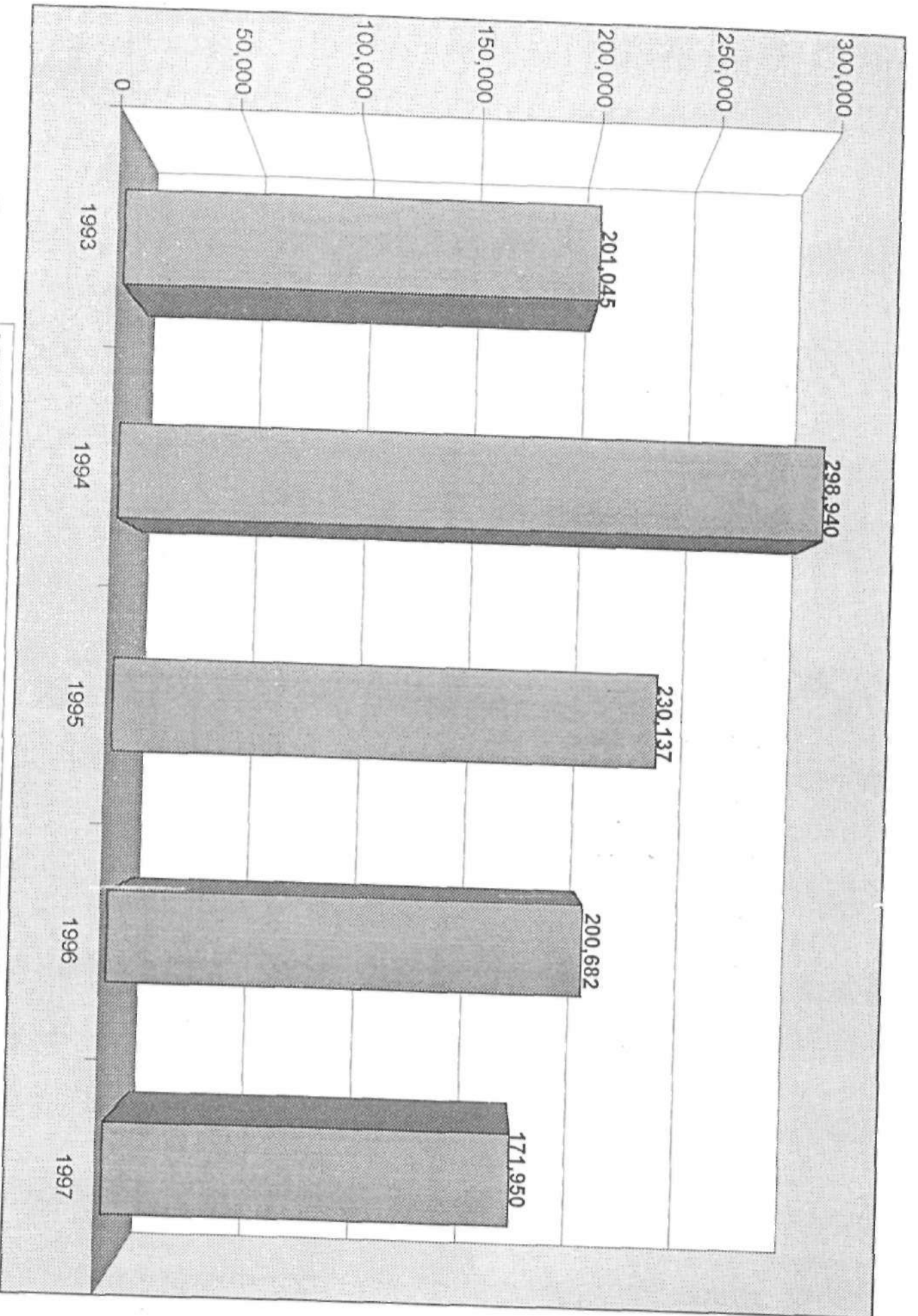


Figure 6:

LEXOTAN 1.5MG x 30s: SALES IN UNITS (1993 - 1997)

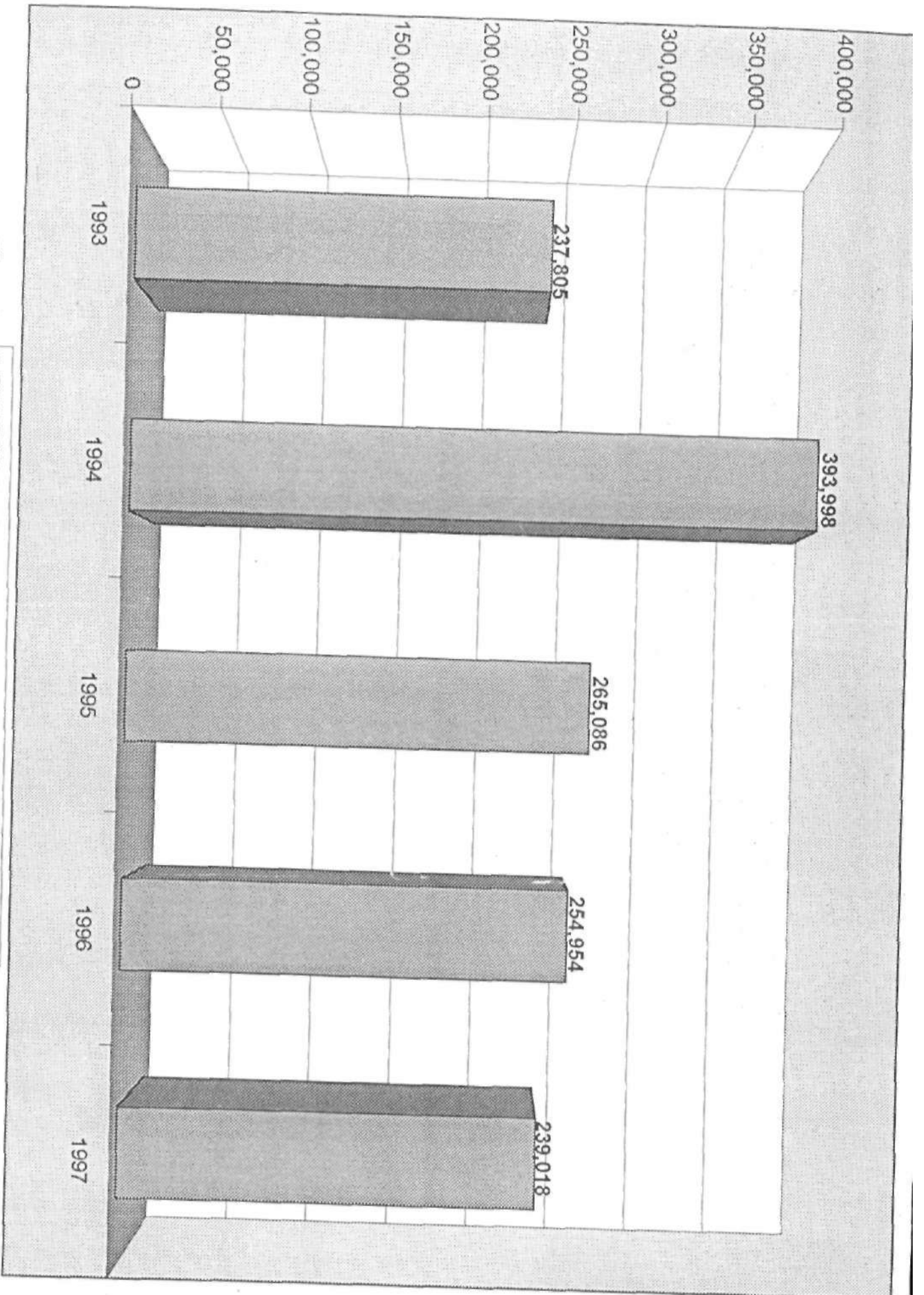


Figure 7: LEXOTAN 3MG x 30s: SALES IN UNITS (1993 - 1997)

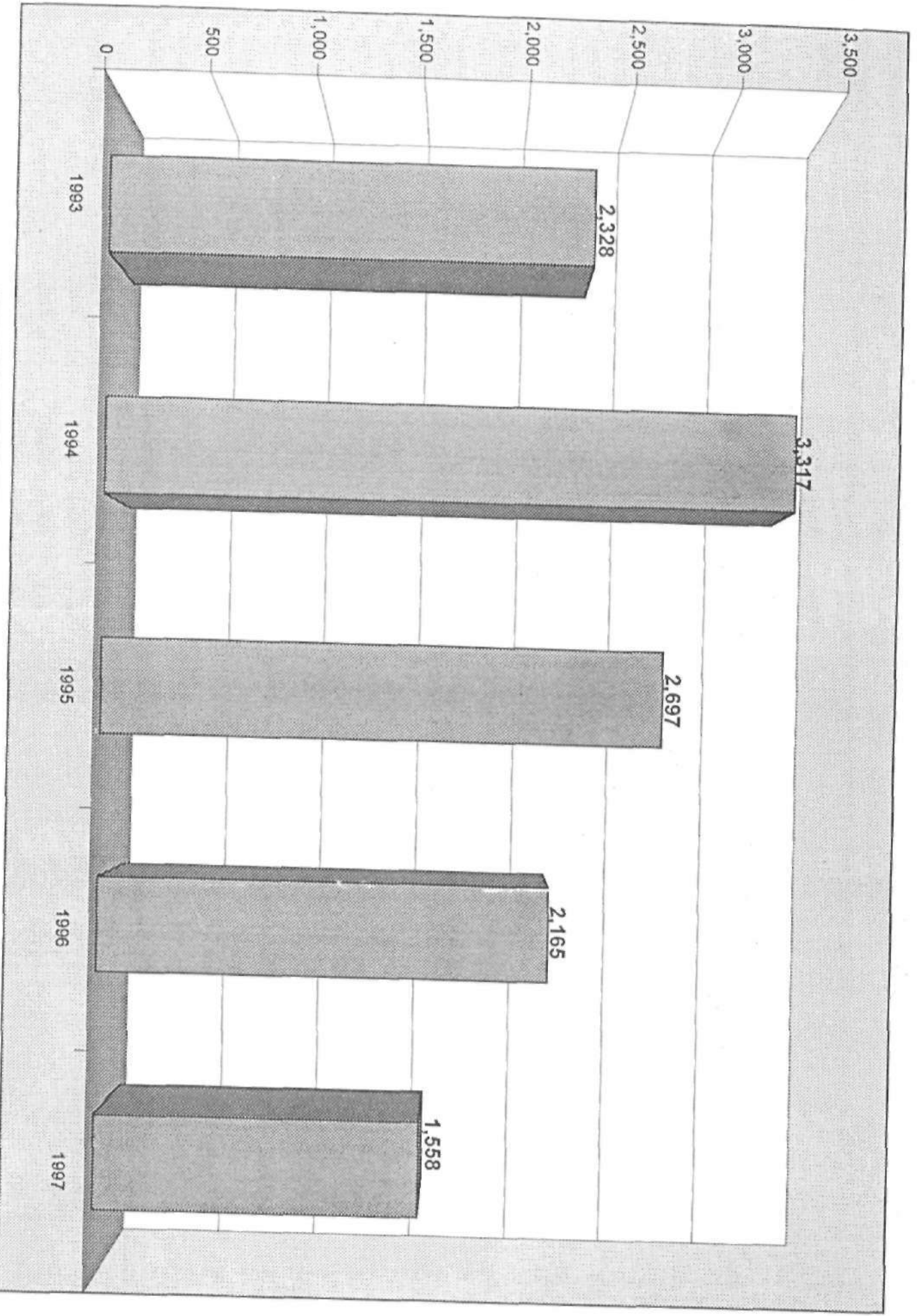


Figure 8:

LEXOTAN 1.5MG X 500s: SALES IN UNITS (1993 - 1994)

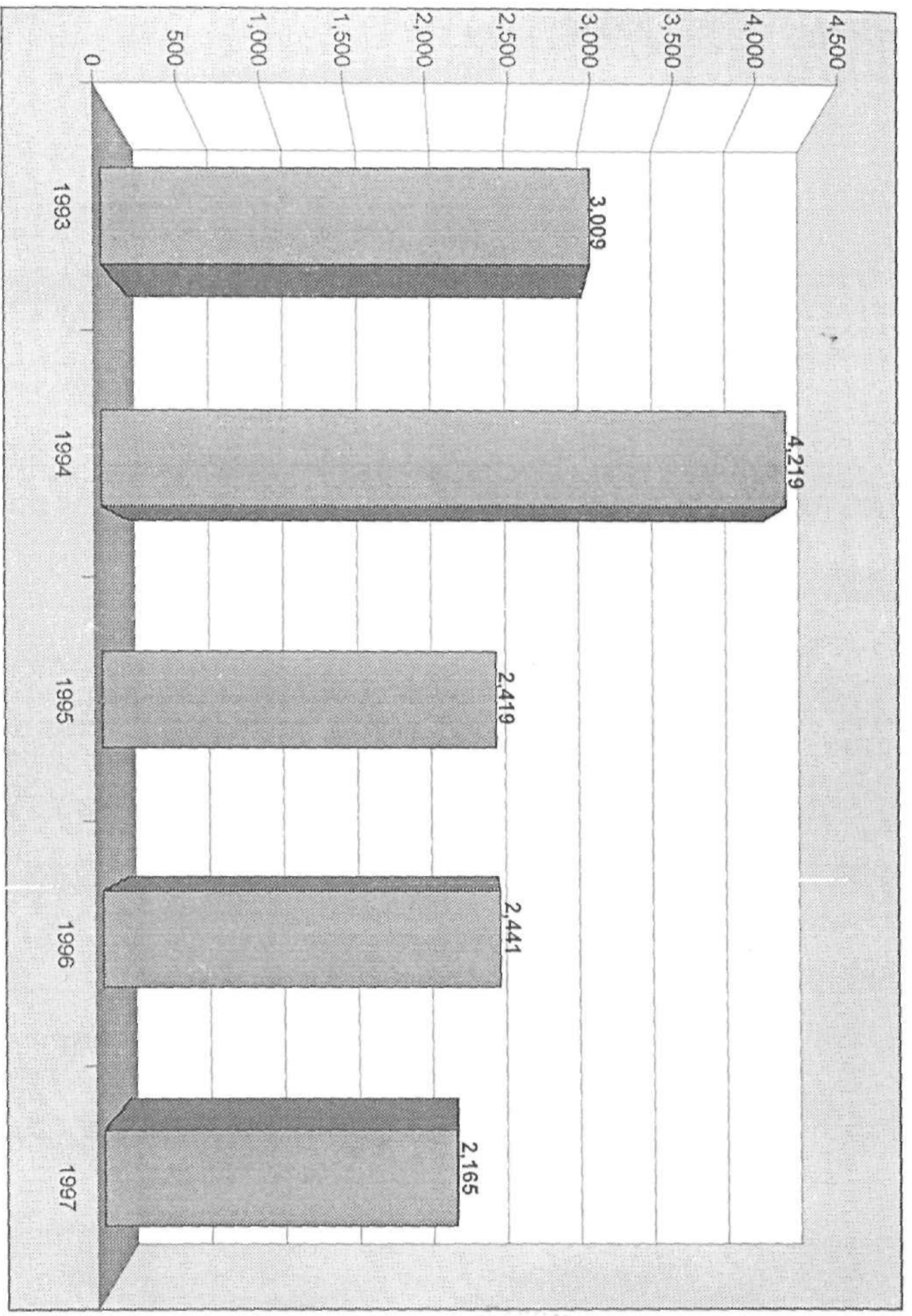


Figure 9:

LEXOTAN 3MG x 500s: SALES IN UNITS (1993 - 1997)

## CHAPTER SIX

### CONCLUSION AND RECOMMENDATION

#### 6.1 SUMMARY

This study has looked at the issue of drug abuse very closely especially as it regards Benzodiazepines. Previous works have been consulted and it is confirmed that it is of importance when considering benzodiazepines. However there are other significant class of drugs with high abuse potentials to be considered. Benzodiazepines are strongly considered because of their impact on emotion and dependence liability.

Roche Nigeria Limited is a multinational pharmaceutical company with subsidiaries in all the continents of the world and more than 100 countries.

It is ranked amongst 10 top pharmaceutical companies in Nigeria and has recorded consistent sales growth in the period 1993-1997.



It manufactures and markets Benzodiazepines, Lexotan is the principal drug in this class and is the second ranked product in its portfolio and accounted for over 15% of its turnover during the study period 1993-1997.

The popularity of the brand in medical practice has drawn the attention of the regulatory agencies (NAFDAC and NDLEA) in the period 1995 - 1997 and their activities in the trade channel has caused fear and discouraged patronage by wholesalers and retailers. This has severally impacted on the units of Lexotan sales during the period despite increased value sales which is attributable to inflation driven price increase.

Data relating to all these parameters were collected in the course of the study and analysed.

The need for wholesalers and retailers to adhere to the guidelines and regulations governing the sale of benzodiazepines cannot be overemphasised and adherence will greatly curb the excesses of the operatives from the regulatory agencies.

## **6.2 CONCLUSION**

The peak of increased regulatory activities in 1995 correlated with the decline in sales during the year and subsequently. As far as Benzodiazepine marketing is concerned, other than the core of the marketing parameters (4ps of marketing), the management of issues and positive relationship with the regulatory agencies will play a significant role. Moderation of their activities favourably has short term and long term benefits to Roche (Nigeria) Limited as it concerns the marketing of Benzodiazepines/Lexotan. Education is very important so that each party (regulatory agencies, Roche (Nigeria) Limited and trade channels) can brace up to her responsibilities.

## **6.3 RECOMMENDATIONS**

For Roche (Nigeria) Limited to remain successful in the marketing of Benzodiazepines/Lexotan, the relationship with the NAFDAC and NDLEA is crucial. Improved relationship with these agencies will ease the disruptions of the distributive channel, improve their positive perception and leading to

improved sales. Relationship marketing which will ensure the involvement of these agencies in some marketing programmes will be profitable in the long term.

Roche (Nigeria) Limited needs to be understood as a partner in progress with regards to drug abuse (which is the primary concern of the agencies). Roche should help fund some drug abuse programmes of these agencies.

One the greatest problem with the wholesalers and retailers is their inability to keep record of form K (Appendix D). They should be educated on the importance. It is this deficiency that make them vulnerable to extortion from over zealous operatives leading to the state of fears.

Benzodiazepines are Ethical drugs and they are psychotropic drugs, hence they are drugs that must be dispensed only on Doctors prescription.

Roche (Nigeria) Limited should ensure that the drugs are sold to registered pharmaceutical wholesalers as it has always done.

The company should educate her customers (wholesalers and retailers) on the need to sell to genuine person or persons and keep prescribed records.

Regular consultations should be held with NAFDAC and NDLEA on best methods of preventing illicit use of benzodiazepines and discuss excesses of their operatives where they exist.

Implementation of these far reaching recommendations will arrest the decline in Lexotan sales and even reverse to growth once more as it was from 1993 to 1994.

This will also ensure that patients who genuinely require these drugs will have them uninterrupted.

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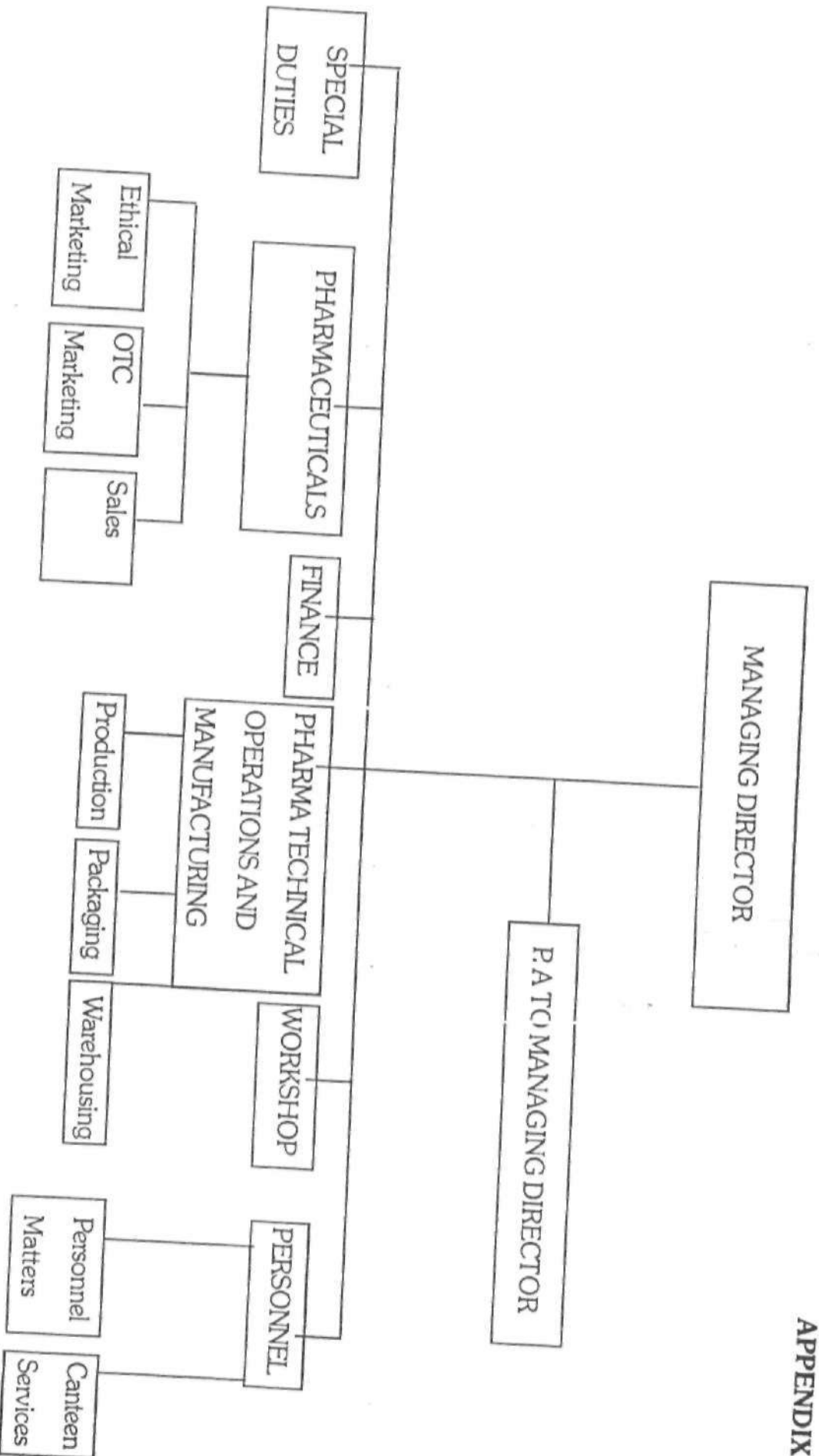
Roche, A company History 1896 - 1996



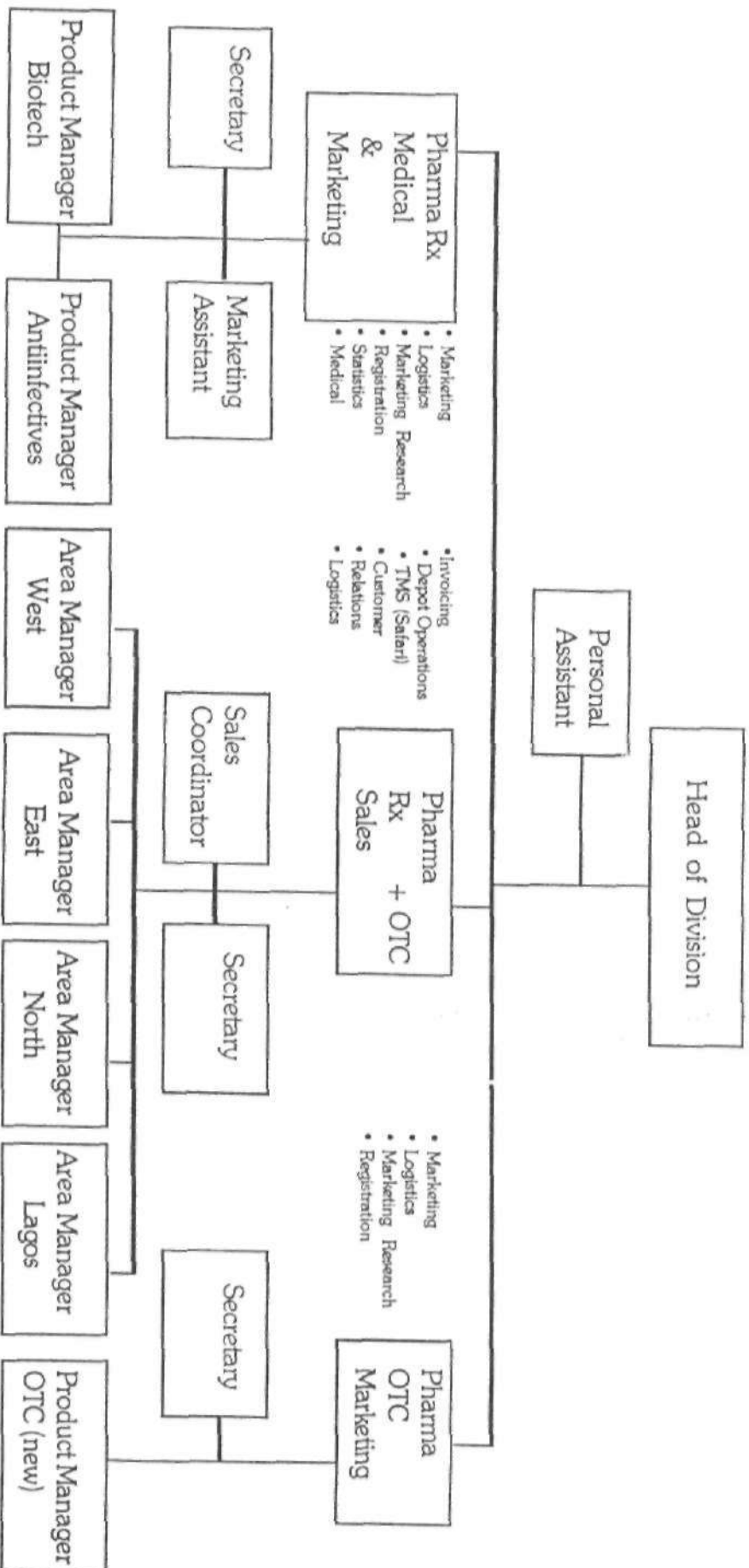
## TOP 10 NIGERIAN PHARMACEUTICAL COMPANIES' TURNOVER (1994-1998)

COMPANY/MARKET	1994			1995			1996			1997			1998				
	Sales N'mio	Market Shares (%)	Rel. Growth ± (%)	Sales N'mio	Market Shares (%)	Rel. Growth ± (%)	Sales N'mio	Market Shares (%)	Rel. Growth ± (%)	Sales N'mio	Market Shares (%)	Rel. Growth ± (%)	Sales N'mio	Market Shares (%)	Rel. Growth ± (%)		
1 PFIZER / NEIMETH	280.0	11.8	78.3	499.1	12.9	723.5	12.8	224.4	45.0	736.5	13.4	13	1.8	990.0	17.5	253.5	34.4
2 MAY & BAKER	260.0	10.9	66.0	431.6	11.2	591.7	10.5	160.1	37.1	693.7	12.6	102	17.2	826.7	14.6	133.0	19.2
3 EVANS	273.6	11.5	45.5	398.5	10.3	544.3	9.6	145.8	36.6	651.9	11.9	107.6	19.8	595.0	10.5	-56.9	-8.7
4 N.G.C.	324.0	13.6	33.3	431.8	11.2	575.1	10.2	143.3	33.2	615.7	11.2	40.6	7.1	575.0	10.1	-40.7	-8.6
5 SKB	166.7	7.0	123.5	372.5	9.6	581.8	10.3	209.3	66.2	613.6	11.2	31.8	5.5	396.0	7.0	-217.6	-35.5
6 GLAXOWELLCOME	151.4	6.4	72.1	260.6	6.7	444.6	7.9	184	70.6	560.0	10.2	115.4	26.0	638.0	11.3	78.0	13.9
7 ROCHE	301.5	12.7	34.7	406.2	10.5	532.6	9.4	126.4	31.1	508.9	9.3	-23.7	-4.4	704.1	12.4	195.2	38.4
8 CIBA GEIGY (SNCCU)	121.0	5.1	60.6	194.3	5.0	269.3	4.8	75	36.6	188.5	3.4	-80.8	-30.0		0.0	-188.5	-100.0
9 SWISSCO (SANDOZ)	85.9	3.6	119.0	188.1	4.9	206.7	3.7	18.6	9.9	150.4	2.7	-56.3	-27.2		0.0	-150.4	-100.0
10 PHARMADDEKO	104.6	4.4	59.3	166.6	4.3	185.0	3.3	18.4	11.0	135.2	2.5	-49.8	-26.9		0.0	-135.2	-100.0

APPENDIX B



# Pharma Division



**APPENDIX D**

**NARCOTICS DISPOSAL RECORD**

S/N	Date	Name and quantity of poisons disposed off	Name and address of receiver	Purpose for which poison is required	Signature of receiver	Signature/name of person introducing receiver	Signature of Pharmaceutical chemist