An Evaluation of the Impact of Legislative Changes on Stakeholders in the South African Pharmaceutical Industry

By

Premakanthie Rosemary Laban

Submitted in Partial Fulfillment of the Requirements for the Degree of
MASTERS IN BUSINESS ADMINISTRATION

Graduate School of Business, Faculty of Management
University of Natal (Durban)

Supervisor: Prof. Elza Thomson

July 2003

CONFIDENTIALITY CLAUSE

1 September 2003

TO WHOM IT MAY CONCERN

RE: CONFIDENTIALITY CLAUSE

Due to the strategic importance of this research, it would be appreciated if the contents remain confidential and not be circulated for a period of five years.

Sincerely

PR LABAN

DECLARATION

This research has not been previously accepted for any degree and is not being currently submitted in candidature for any degree.

Signed _____

Date 16/9/2003

ACKNOWLEDGEMENTS

There are those without whom I would have not survived this journey:

- Gona, Dasagen, Vanessa & Jessica: your patience is appreciated
- Daddy, Tutu and Neela: your memory lingers and strengthens me
- Neera, Michelle, Tanya and Lisa & Shaquir : always a support

A word of appreciation to my supervisor, Prof Elza Thomson, for her input and to Jayshree whose notes were invaluable.

A special word of thanks to Naresh, Joe and Razi, who made this course happen, to Sumaya and Ray for tutoring in accounting and to Vijay whose notes were a big help. To Harv and Les, thank you for being there.

Finally, to Ivan: Thank you for all your help with everything.

ABSTRACT

Changes in the health sector in South Africa have been widespread since 1994 with restructuring of the public sector being the focal point of legislation. The limelight has recently shifted focus to the health sector with the Medicine and Related Substances (MRSCA) Amendment Act, 59 of 2002 in which generic substitution was finally promulgated, after disputes in the international arena about patent rights, due to the government's policy on parallel imports. Section12 of Pharmacy Act 90, which forms part of the Act is an attempt to further regulate the industry, that eventually became effective this year. This legislation addresses issues of sampling and perverse incentives and calls for the establishment of a Marketing Code for the pharmaceutical industry. The South African government has, as part of the amendment, called for input from all stakeholders including: trade associations, the pharmaceutical industry and the medical profession. All role players were invited to be part of the decision-making process as to what should constitute the Marketing Code and its' regulatory body.

The Society of Psychiatrists (SASOP), an affiliate of the South African Medical Association (SAMA), has not yet prepared a response to SAMA for submission to government with regard to the Marketing Code, in the field of central nervous system (CNS) products. The impact of the banning of samples on psychiatric private practice is not known and there is insufficient data available about the marketing activities of drug companies and the link to the prescription habits of medical professionals. Further, to date, there has been no canvassing of opinions with regard to the impact of the legislation on the consumer. In this case study analysis, an evaluation of the impact of legislative changes in the South African pharmaceutical industry is made. Recommendations as to what should constitute a Marketing Code for the pharmaceutical industry are highlighted.

TABLE OF CONTENTS PAGE

1. CHAPTER ONE: INTRODUCTION **1**

1.1 INTRODUCTION 1

1.2 BACKGROUND 1

1.3 THE STAKEHOLDERS 3

1.3.1 The Medical Profession 3

1.3.2 The South African Society of Psychiatrists 3

1.3.3 Pharmaceutical companies 3

1.3.3.1 Role Players in the Antidepressant Market 4

1.3.4 Pharmacists 5

1.3.5 The South African Government 5

1.3.6 The Consumer 5

1.4 THE MARKET 6

1.4.1 The Antidepressant Market 7

1.5 THE LEGISLATION 8

1.6 THE HEALTH PROFESSIONALS COUNCIL'S RESPONSE 9

1.7 THE INTERNATIONAL PERSPECTIVE 10

1.8 MOTIVATION FOR THE CASE STUDY 10

1.9 RESEARCH OBJECTIVES 12

1.10 METHODOLOGY 13

1.10.1 Design Type 13

1.10.2 Data Collection and Sources 14

1.11 EVALUATION OF THE STUDY 14

1.11.1 Credibility 15

1.11.2 Validity 15

1.11.3 Reliability 15

1.11.4 Transferability 15

1.11.5 Triangulation 16

1.12 LIMITATIONS OF THE STUDY 16

1.13 CONCLUSION 17

2. CHAPTER TWO: STRATEGIC THEORY AND STRATEGIC ANALYSIS **18**

2.1 INTRODUCTION 18

2.1.1 Pharmaceutical companies in the antidepressant market 19

2.1.2 Definitions of Strategy 21

2.1.3 Strategic Management 23

2.1.4 Strategic Planning 24

2.2 ENVIRONMENTAL ANALYSIS 26

2.2.1 The micro-environment 27

2.2.2 The macro-environment 27

2.2.3 Assessing the nature of the environment 28

2.2.3.1 Assessing the dynamics of the environment 28

2.2.3.2 Scenario-based analysis 29

2.2.3.3 Analyzing environmental uncertainty 30

2.2.3.4 Analyzing the co-operative environment 31

2.2.4 Auditing environmental influences 32

2.2.4.1 PEST Analysis 32

2.2.4.2 Porter's Diamond 33

2.2.4.3 Analyzing Stakeholder Reactions 35

2.2.5 Industry Life Cycle 37

2.2.6 Analyzing the role of government 39

2.2.7 Analyzing government and industry relations 40

2.2.8 Analyzing the intensity of competition in an industry 41

2.29 Competitive rivalry 41

2.3 IDENTIFYING COMPETITIVE POSITION 43

2.3.1 Market Segmentation 43

2.3.2 Perceived Value 45

2.3.3 Competitor Analysis 46

2.4 ANALYZING THE COMPETITIVE ENVIRONMENT: FIVE FORCES ANALYSIS 47
2.4.1 Threat of New Entrants 48
2.4.2 The Power of Buyers and Suppliers 49
2.4.3 The Threat of Substitutes 50
2.5 ANALYZING CORE COMPETENCES AND STRATEGIC CAPABILITY 50
2.5.1 Assessing Competence 50
2.5.2 The BCG Matrix 52
2.5.3 Identification of Key Issues 53
2.5.3.1 SWOT Analysis 53
2.5.3.2 Critical Success Factors 54
2.6 INTERNAL ANALYSIS 54
2.6.1 Resource Audit 55
2.6.2 Value chain analysis 55
2.7 STRATEGIC CHOICE 55
2.7.1 The SWOT Matrix 55
2.7.2 Generic Strategies 57
2.7.3 Grand Strategies 58
2.7.3.1 Market development 58
2.7.3.2 Product development 59
2.7.3.3 Concentric diversification 59
2.7.3.4 Conglomerate diversification 59
2.7.3.5 Horizontal integration 60
2.7.3.6 Vertical integration 60
2.7.3.7 Strategic Alliances 60
2.7.4 McKinsey Model 61
2.8 STRATEGIC EVALUATION 62
2.8.1 Suitability 62
2.8.2 Acceptability 62
2.8.3 Feasibility 63

2.9 STRATEGIC CHANGE 63
2.9.1 Enforced change 64
2.9.2 Expansion strategies 64
2.9.2.1 The Market Options Matrix 64
2.9.3 Strategic change in government agencies 66
2.10 STRATEGIC OPPORTUNITIES FOR PROVIDERS OF SERVICE 66
2.11 CUSTOMER-DRIVEN STRATEGY 67
2.11.1 Customer Profiling 68
2.11.2 Branding 69
2.11.3 Communicating with customers 69
2.11.4 Strategic pricing and value for money

3. CHAPTER THREE: THE SA PHARMACEUTICAL INDUSTRY & LEGISLATIVE CHANGES 73
3.1 INTRODUCTION 73
3.1.1 History and Background 73
3.1.2 The Issues Involved 74
3.2 THE ECONOMICS OF PRICING 75
3.2.1 SA Public Sector spending and prices 76
3.2.2 Private sector spending: medical aid 79
3.2.3 The cost of drugs in SA 79
3.2.3.1 Price surveys 79
3.3 THE DOH'S DRUG POLICY 81
3.3.1 The economics of drug policy options 82
3.3.2 Government interventionist policies 83
3.4 THE RELATIONSHIP BETWEEN STAKEHOLDERS 83
3.4.1 Producer Price Control Measures 84
3.4.2 Distribution Chain Cost Controls 85

3.4.3 Bulk Purchase Measures 88
3.4.4 International Trade Agreement Relief Measures 90
3.4.5 Demand Side Measures 92
3.5 THE MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT 92
3.5.1 Supply of Medicines in South Africa 92
3.5.2 Parallel Imports 92
3.5.3 Prescribing Generic Equivalents 93
3.5.4 Pricing Committee 93
3.5.5 Bonusing and Sampling 93
3.5.6 Code of Ethics 94
3.5.7 Safety Regulations 94
3.6 THE HEALTH PROFESSIONALS COUNCIL OF SOUTH AFRICA'S RESPONSE 94
3.7 THE IMPACT OF THE NEW LEGISLATION ON PHARMACY PRACTICE 71
3.8 DEFENDING THE MEDICINES CONTROL AMENDMENT BILL 98
3.9 PHARMACY ACT 90 98
3.9.1 Sampling 99
3.9.2 Generic Substitution 99
3.10 CONCLUSION 99

4. CHAPTER FOUR: LESSONS FROM INTERNATIONAL EXPERIENCES 101
4.1 INTRODUCTION 101
4.2 THE GENERIC DEBATE 102
4.2.1 The World Health Organization 103

4.3 PRIVATE SECTOR DEVELOPMENT IN LOW-INCOME COUNTRIES 105
4.3.1 Characteristics of the private health sector 105
4.3.2 Influencing Consumers 106
4.3.3 Social Marketing 107
4.3.4 Use of Vouchers 108
4.3.5 Consumer Protection 107
4.3.6 Influencing private providers 109
4.3.6.1 Training 109
4.3.6.2 Regulatory and participant Approaches 110
4.3.6.3 Resourcing Providers 110
4.3.6.4 Comprehensive Approaches 110
4.3.7 Restructuring the Market 111
4.3.8 Government stewardship 111
4.3.9 Contracting Out Services 111
4.3.10 Regulating the market 112
4.3.11 Comprehensive restructuring 112
4.3.12 Conclusions regarding developing countries 113
4.4 THE US MARKET 113
4.5 THE UK MARKET 115
4.5.1 Selectively reported results 116
4.5.2 The Backlash in UK and Europe 117
4.6 A MARKETING CODE FOR THE US 117
4.7 IS A MARKETING CODE NECESSARY 119
4.7.1 Interactions with representatives 120
4.7.2 Sampling 120
4.7.2.1 Misuse of samples 121
4.7.3 Detailing by representatives 121
4.7.3.1 Detail Aids 122
4.7.4 Prescription Habits 122

4.7.5 Journal Advertising 123
4.7.6 Promotional Gifts 124
4.8 CONCLUSION 124

5. CHAPTER FIVE: RECOMMENDATIONS AND CONCLUSION 125
5.1 INTRODUCTION 125
5.2 GENERIC SUBSTITUTION 125
5.2.1 The NAPM's perpective on generic medication 128
5.3 THE NATIONAL DRUG POLICY 129
5.4 A CODE OF CONDUCT FOR THE PHARMACEUTICAL INDUSTRY 130
5.5 THE PLACE OF PRIVATE PRACTICE 130
5.6 PARALLEL IMPORTS 133
5.7 CLARITY OF LEGISLATION 133
5.8 A MARKETING CODE 136
5.9 CONCLUSIONS 139

6. REFERENCES 141

7. ABBREVIATIONS 144

8. GLOSSARY 145

9. APPENDICES 146

LIST OF TABLES **PAGE**

Table 2.1 Analyzing environmental turbulence 28

Table 2.2 Stakeholders and their expectations 36

Table 2.3 Lifecycle Model 38

Table 2.4 New or underutilized segment gaps 45

Table 2.5 Functional capabilities in an industry Life cycle 50-51

Table 3.1 Provincial expenditure on drugs per Financial year 77

Table 3.2 Relative contributions to the final Selling price of a drug in the private sector 87

LIST OF FIGURES **PAGE**

Figure 2.1 Andrews strategy model 22

Figure 2.2. Components of the strategic management Process 23

Figure 2.3 A summary model of the elements of Strategic management 24

Figure 2.4 Gap analysis 25

Figure 2.6 The Marketing Environment 27

Figure 2.7 Analyzing the co-operative environment 31

Figure 2.8 Porter's Diamond 34

Figure 2.9 Industry Life Cycle Model 38

Figure 2.10 Porter's Five Forces Model 47

Figure 2.11 BCG Matrix 53

Figure 2.12 SWOT Matrix 56

Figure 2.13 Generic strategies matrix 57

Figure 2.14 Ansoff's product/market matrix 58

Figure 2.15 McKinsey's Model 61

Figure 3.1 Interlocking contributions to drug access 76

Figure 3.2 Price of a basket of 1000 drugs used in private Hospitals plotted against CPI 79

Figure 3.3 Traditional distribution channels for medicines 86

LIST OF GRAPHS **PAGE**

Graph 5.1	Antidepressant use in SA	124
Graph 5.2	Cost of antidepressants in SA	125

APPENDICES **PAGE**

Appendix One: The MRSCA 146

Appendix Two: PEST ANALYSIS 147

Appendix Three: SWOT ANALYSIS 148

CHAPTER ONE: INTRODUCTION

1.1 INTRODUCTION

The South African (SA) pharmaceutical industry has historically relied on the 'traditional' marketing mix and relationship marketing to conduct its' business. Recent changes in legislation by the SA government include the Medicines and Related Substances Amendment Act (MRSCA) that was initially formulated in 1997, but only registered as Act 59 of 2002, in the Government Gazette, in January 2003. This was as a result of a legal challenge by the international community to the controversial areas in the Act, which advocates parallel imports and generic substitution of drugs and the licensing of dispensing doctors.

The Act also seeks to regulate the marketing behaviour of the pharmaceutical industry in several areas by banning the practice of sampling and the provision of bonus and rebate schemes, and strictly controlling sponsorship of medical education events, all of which have been considered perverse incentives. Provision is made within the Act for the introduction of a marketing code and a regulatory body to monitor its implementation. This chapter will provide a background to the legislative changes and its potential impact on stakeholders. The research objectives, methodology and limitations of the case study analysis are also discussed.

1.2 BACKGROUND

The South African pharmaceutical industry has been the focus of international attention since 1997, with widespread changes in legislation with regard to generic medication and dispensing doctors. One of the changes to legislation that has evaded the limelight until recently has been what was called Section12 of Pharmacy Act 90 that was included in Act 101 of 1965, in 1997. This legislation that in part, calls for the establishment of a Marketing Code for the pharmaceutical industry has been debated in the National Assembly and forms part of the Medicine and Related Substances (MRSCA) Amendment Act. The South African government has, as part of the amendment, called for input from all stakeholders including: trade associations, the pharmaceutical industry and the medical profession. All role players were invited

to be part of the decision-making process as to what should constitute the Marketing Code and its' regulatory body.

The South African Society of Psychiatrists (SASOP), an affiliate of the South African Medical Association (SAMA), has not yet prepared a response to SAMA for submission to government with regard to the Marketing Code, in the field of central nervous system (CNS) products. There is insufficient data available on response to marketing activities, the level of brand awareness amongst psychiatrists and the link between the marketing strategy of pharmaceutical companies and the prescription habits of medical professionals. Further, to date, there has been no canvassing of opinions with regard to the legislation amongst service providers or any exploration of the impact it would have on stakeholders.

The current value of the pharmaceutical industry is over R10bn. Public health care, funded by government accounts for most of the demand but only a small percentage of the pharmaceutical sector's value and has little impact at present on the marketing strategy of pharmaceutical companies. Most of the industry's revenue comes from the private sector, which is funded mainly by member's contributions to medical aid schemes, so private practitioners are regarded by the industry as their primary focus (Internet 1).

The local pharmaceutical industry is highly competitive in nature and companies' market shares often run neck and neck. This is especially so in the market for CNS products, where there is a race for innovative products and creative marketing strategies by the major role players. These include the leading pharmaceutical companies internationally, who have South African subsidiaries. Pfizer South Africa, Lilly South Africa, Lundbeck South Africa and GlaxoSmithKlein operate alongside South African companies like Adcock-Ingram and Aspen. In the CNS product portfolio, the branded antidepressant market is under attack from a growing generic market, which has the support of government and most medical aid schemes. In its response, the bigger industry players have increased the capacity of or established generic divisions, even though there is an international trend of growth within the branded product market, with new products being launched and strong 'pipelines' in most market leader's research facilities (Internet 2).

The marketing activities of the local industry have historically had to be consistent in quality and content with the global industry. Multinational companies (MNC's) usually have their strategic marketing portfolios based at head office with regional management platforms that incorporate the local ethos into the global corporate vision. The restrictive nature of the new legislation poses a threat to that strategy and product managers will have to strategically respond to the changes to ensure that they retain and grow market share.

In this case study analysis, the impact of the legislative changes on stakeholders within the antidepressant market was evaluated. An assumption was made that this construes a fair reflection of the response of the industry as a whole. Opinions regarding a Marketing Code for the pharmaceutical industry were canvassed and recommendations formulated.

1.3 THE STAKEHOLDERS

The stakeholders in the SA pharmaceutical industry include the medical profession, the SA government, the pharmaceutical companies, pharmacists and consumers whose interests in the private sector are represented by medical aid schemes and consumer advocacy groups.

1.3.1 The Medical Profession

SAMA is a professional association for medical doctors without any statutory or disciplinary powers. It is also a registered trade union for its members employed in the public sector. At present some 70% of doctors in both the public and private sectors are voluntary members of the association, which is registered as an independent, non-profit, Section 21 company. The Association's activities focus on both professional and business aspects of medical care in SA. Its stated goal is "to influence the health care environment to meet the needs and expectations of the community by promoting improvements to health reform, policy and legislation" (Internet 3).

1.3.2 The South African Society of Psychiatrists

The South African Society of Psychiatrists is affiliated to the Health Professionals Council of South Africa. It is not a statutory body but an association of psychiatrists that is registered as a non-profit organisation. It has a membership of 360 psychiatrists, including retired psychiatrists and psychiatrists residing abroad and is representative enough to be regarded as the 'voice' of psychiatry in SA. It has good relationships internationally with the American Psychiatric Association and the Royal College of Psychiatry. Its stated aim is to protect the rights of patients with psychiatric illnesses and assist its members in the practice of the discipline of psychiatry. The Private Psychiatrists of South Africa (PPSA), an affiliate of SASOP, with executive committee representation in the Private Psychiatrists Interest Group, is a registered Company that represents psychiatrists in private practice. The PPSA, which has a Board of Directors who are representative of all the provinces, have been tasked with lobbying with the medical aid industry and the Board of Healthcare Funders (BHF) regarding tariffs for psychiatrists and medical aid limits on psychiatric benefits (Internet 2).

1.3.3 Pharmaceutical Companies

The pharmaceutical industry in South Africa is represented by the National Association of Pharmaceutical Manufacturers (NAPM), which deals largely with local pharmaceutical companies' concerns, and the Pharmaceutical Manufacturers Association (PMA), which deals with international concerns of companies with a presence in SA. It also represents the interests of local companies, on a global level (Internet 1). The major role players in the branded local antidepressant market include Lundbeck SA, Pfizer SA, Lilly SA and GlaxoSmithKlein (Internet 1).

1.3.3.1 The Roleplayers in the Antidepressant Market

The major pharmaceutical companies that operate in the SA antidepressant market are Lilly SA with its product Prozac, Lundbeck SA marketing Cipramil, GlaxoSmithKlein with Aropax and Pfizer SA, with Zoloft. Other players include Wyeth SA, with Efexor, Donmed with Remeron and Solvay with Luvox. There are several new entrants into the market who have recently launched products from companies with a limited investment in CNS products and a restricted marketing budget. Other major players with a CNS product portfolio include Janssen-Cilag and

AstraZeneca SA, who do not compete in the antidepressant market but have other branded products which have relevance to psychiatry (Internet 1).

1.3.4 Pharmacists

The interests of pharmacists in South Africa are represented by the Pharmaceutical Society of South Africa (PSSA). The legislative changes have increased the role that pharmacists play in the dispensing of medication, allowing for independent generic substitution of ethical prescriptions. There have also been revisions made to pricing methods used in the industry, with a change from the cost plus system of mark-ups on drugs at the pharmacy level, to a dispensing fee that is fixed at a flat rate, which has also impacted on pharmacy practice in South Africa.

1.3.5 The South African Government

The responsibility for the development and implementation of legislation governing the health care sector in South Africa rests with the Ministers of Health and the Departments of Health nationally and provincially. The government has had to assume the responsibility of devising the infrastructure that would meet the health care needs of the population and the area of medicines control has been its greatest challenge. The reality is that even essential medicines remained out of reach of the majority of the population, due to the cost factor and the situation had to be urgently addressed, within the constraints of the resources allocated to the Health Budget.

1.3.6 The Consumer

The consumer in the private sector is usually represented by medical aid schemes in any negotiation forum. The major medical aid schemes in South Africa include Medscheme, which acts as administrator for other medical aids, National Medical Plan (NMP), Discovery Health, Medihelp, Bankmed and Mx Health, which administers Polmed. Consumers in the public sector who could not afford private care, have had to utilize the services provided by the Department of Health (DOH).The biggest concern about the medical insurance industry in South Africa has been its adoption of the managed health care model, which has historically failed as a system of cost-effective health care delivery, in other countries, like the US.

The Consumer Council and various public advocacy groups do monitor the situation and assume responsibility to be the voice of the consumer in South Africa. In the health sector, there has been minimal input from these advocacy groups at the level of legislation governing health services, except for media coverage of the major issues at stake, relevant to HIV illness and generic medication. In the antidepressant market, there is a fairly active Anxiety and Depression Support Group that offers advice to patients nationally via a toll-free line that is partly funded by the pharmaceutical industry and has the support of SASOP. However, the service is mainly confined to assisting patients and there is minimal focus on legislative policy and how it impacts on patients' rights (Internet 2).

1.4 THE MARKET

In the year 2000, the value of drug sales in South Africa was R8,25 billion. Public sector sales made up approximately 24%, translating to R59,36 per person without a medical aid scheme. The per capita expenditure on prescription drugs in the private sector was approximately R800,29, excluding over-the-counter (OTC) medicines sales, which constituted only 6% of the total value. Dispensing doctors were only responsible for 15% of drug sales (Internet 1).

The current value of the pharmaceutical industry lies in the branded sector of the market, although government support for generic medication is making inroads. SA currently uses about 20% of generic drugs compared to the United States, where 60% of pharmaceutical sales are generic products. The generic market is expected to grow substantially over the next few years, especially in the light of legislative support. The alternative medicines market, which is not regulated at all, is growing at 15% per annum. This represents a concern for all role players in the ethical drug market as South Africa is being viewed as an open market for 'natural' products, many of which have never undergone any testing for human consumption and have had no regulatory responsibility in terms of standards, in their country of origin. South African companies in the alternative health market like Herbex, have seen a sudden growth spurt in the market, for drugs like St John's Wart, that have been advocated to have antidepressant properties. There is also a huge market for weight loss related and libidinal products and the Advertising Standards Authority is now investigating

claims made by some of these companies with regard to the efficacy of their products (Internet 1).

1.4.1 The antidepressant market

The antidepressant market has particularly been at the forefront of the current battle for brand recognition both locally and internationally. In the US, the 20 best-selling prescription medications in 2001 included three antidepressants: Zoloft, Paxil and Prozac. GlaxoSmithklein's Paxil (Aropax in SA) and rival Pfizer's Zoloft each had about $2 billion in U.S. sales in 2002. According to a marketing-research service that tracks consumer advertising, marketers spent $184.5 million in 10 months from January through October 2001 (Internet 4). The South African situation is as competitive and invested in branded products.

The government's decision to proactively support generic medication has impacted on this market within the private sector, as most medical aid schemes now subscribe to the essential drug list (EDL) that has been compiled by government after consultation with the public health sector. Medical aid schemes now only pay towards drugs registered on the Maximum Medical Aid Price (MMAP) list, which is essentially a replica of the EDL. Should consumers request branded products, medical aids require that difference in costs to be self-funded.

One of the difficulties with this situation for service providers is that there are only five antidepressants listed in the EDL. All of them have generic substitutes available and four of them may place the consumer at risk because of their side effect profile. A further complicating factor in the private sector, for antidepressant use, is that most medical aid schemes have annual limits on medication expenditure. Branded products cost more for a year's treatment than these limits and consumers have historically relied on samples, or loyalty programs from the pharmaceutical industry to meet the lack. These samples were issued as part of structured re-imbursement programs that rewarded compliance and were accompanied by educational information regarding disease and lifestyle management. These programs had the support of service providers and the medical aid industry and are now 'illegal' in that samples may not be issued except under very specific conditions, like research (Internet 1).

1.5 THE LEGISLATION

The Medicines and Related Substances Amendment Act, 2002, Act No. 59, 2002 (Appendix One) states amongst other things that the Act aims to:

- Provide for measures for the supply of more affordable medicines in certain circumstances
- Provide for the generic substitution of medicines
- Provide for the establishment of a pricing committee
- Regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines
- Provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers or distributors
- Regulate the Minister's power to make decisions

The Act includes Section 12 of Pharmacy Act 90 of 1997, which included the following amendments to the previous legislation governing this sector, Act 101 of 1965:

- Bonusing Section 18 A:

  "No person shall supply medicine according to a bonus system, rebate system or any other incentive scheme"
- Sampling Section 18 B:

  "No person shall sample any medicine"
- A code of ethics Section 18 C:

  "The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, prescribe a code of ethics relating to the marketing policies of pharmaceutical companies"

In May 2002, an amendment of Section 18C of Act 101 of 1965 as inserted by Section 12 of Act 90 of 1997 was passed with the following section hereby substituted for Section 18C of the Principal Act:

"The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to a Marketing Code relating to the marketing

practices of pharmaceutical companies. The regulations referred to shall also provide for: the appointment of a body comprising of representatives of trade associations, pharmaceutical industry, consumers and health care providers to enforce the Marketing Code together with Council, the funding of the body referred to and the enforcement of the Code referred to" (Internet 5).

1.6 THE HEALTH PROFESSIONALS COUNCIL'S RESPONSE

The Health Professionals Council of South Africa's (HPCSA) issued a policy on perverse incentives, which was drawn up in response to Act 90 of 1997 (Internet 7). The South African Medical Association (SAMA) responded to the changed legislation by providing guidelines based on Act 90 and the HPCSA's policy statement. The guidelines stipulate that the pharmaceutical industry may not provide samples of any medicine, supply medicine on a bonus, rebate or incentive scheme, pay commission and provide expensive gifts and that health care professionals may not accept any of the above (Internet 6).

Further, doctors may not advertise or encourage the use of medicines, health-related products, hospitals or medical devices in order to promote his/her practice unfairly for improper financial gain. Doctors may not charge fees for seeing medical representatives or request samples, gifts, bonuses and other incentives (Internet 3).

Although the guidelines seem to be a rational approach to the dilemma facing the industry and the profession, the issue is more complicated. The HPSCA requires that all medical professionals participate in continuing professional development (CPD) accreditation programs in order to continue to actively practice in South Africa (Internet 6). The pharmaceutical industry has spearheaded the drive to organize CPD-accredited activities as a service to its customer base. The industry has a presence at all continuing medical education (CME) meetings, journal club meetings, conferences, Independent Practitioner Association (IPA) meetings and symposia. Sponsorship is usually of meals associated with these events but the medical representatives often assume the organizational responsibility for these events combining the marketing of the company's product offering, with CPD activities. The boundaries have thus been consistently blurred between the educational needs of

health care providers and the marketing strategy of the industry. SAMA has indicated that although such sponsorship can continue strict, guidelines that include the removal of product branding have to be abided by. The guidelines still allow for company branding though, which is open to interpretation and hence, manipulation, as most brands are established in the consumer base already.

1.7 THE INTERNATIONAL PERSPECTIVE

International trends in the relationship between the pharmaceutical industry and the medical profession do lend weight to the SA government's perspective on a need to regulate the marketing activities of the pharmaceutical industry:

- U.S. Drug spending increased by 17.1% to $154.5 billion dollars in 2001. One-quarter of this increase was due to a shift to the use of more expensive drugs.
- Pharmaceutical industry profits were 18.5% of revenue in 2001. For the remainder of Fortune 500 companies, median profits were 3.5%.
- Since 1995, the research and development (R&D) staff of US brand- name drug companies have decreased by 2%, while marketing staff have increased by 59%. Currently, 22% of staff are employed in R & D, while 39% are in marketing.
- 46% of physicians reported in a survey that drug representatives are moderately to very important in influencing their prescribing habits.
- In 2000, Merck spent $161 million on advertising for Vioxx, which is more than Pepsico spent advertising Pepsi ($125 million).
- Drug companies spent $15.7 billion dollars on promotion in 2000 including the distribution of $7.2 billion dollars worth of free samples.
- The American Medical Association generates $20 million in annual income by selling detailed personal and professional information on all doctors practicing in the US to the pharmaceutical industry (Internet 7).

1.8 MOTIVATION FOR THE CASE STUDY

The Medicines and Related Substances Amendment Act was developed by the Department of Health in 1997, however, disputes over intellectual property rights by

the international pharmaceutical industry delayed promulgation of the Act until 2002. The controversial areas in the Act involved mandatory generic substitution, the licensing of dispensing doctors and the acceptance of parallel imports. The Department of Health has supported the implementation of the policies within the Bill, resulting in the South African pharmaceutical industry being in a state of flux. To date there has been no evaluation of the impact these legislative changes have had on stakeholders.

Pharmacy Act 90, Section 12 that was incorporated into the MRSCA Act, is impacting on private practice and the marketing practices of the pharmaceutical industry in SA. The SA government has requested input from all the stakeholders including trade associations, the pharmaceutical industry and the medical profession. The South African Society of Psychiatrists (SASOP) has not yet formulated a response with regard to the impact of the legislation on its members. Some of the knowledge gaps that exist due to insufficient data include: brand awareness among psychiatrists within South Africa, the concept of ethical marketing and the link between marketing activities of drug companies and the prescription habits of psychiatrists. Certainly, it appears as if the banning of sampling and incentive schemes will impact on service delivery to the consumer (Internet 2).

The antidepressant market in South Africa is a potential growth area for the economy and the concerns about the Act are that regulation of the industry will be at the cost of growth. The PMA does not have sufficient data from its client base, the service providers, regarding its marketing mix. Existing market research in South Africa in the antidepressant market has focused mainly on new product launches and differences in marketing approach between the different drug companies. Data about advertising and brand awareness among psychiatrists in SA would be invaluable to the PMA and its members in correctly apportioning their marketing budget. Further, South African affiliates of global companies are faced with the challenges of a single exit price policy and fluctuating rand/dollar exchanges, so profit margins within the industry are already pressurized. Accurately pitched marketing strategies would give companies the edge over their competitors (Internet 1).

SASOP's concerns have been two-fold. There is concern over the restrictions placed on branded product usage by medical aid schemes as the consumer is not being afforded the right to the best possible treatment option, which is in keeping with good medical practice. South African psychiatrists also need to acquire clinical expertise with the newer products that are available on the market internationally. In the public sector doctors-in-training have minimal exposure to branded products, which does not prepare them for private practice.

On the other hand, SASOP is concerned about the impact of the marketing practices of the industry on the prescription habits of psychiatrists, especially in the light of the trends in the US, where the industry has taken the lead role in the education of psychiatrists and consumers alike. This has fueled the arguments of the anti-psychiatry movement that are vociferous in their attack on the ethical antidepressant market. The concerns about industry-driven diagnoses and management is legitimate, however, the reality is also that psychiatry remains a discipline with the greatest potential for research and drug discovery, as so much is still unknown. Feedback to SASOP from its members regarding a Marketing Code would be invaluable in determining the course that the relationship between the industry and the service providers in South Africa should take, especially with regard to medical education and research (Internet 2).

1.9 RESEARCH OBJECTIVES

This case study analysis therefore aims to assess the impact of legislative changes on stakeholders in the pharmaceutical industry, by exploring the question "Will the new legislation benefit stakeholders?" The study aims to evaluate the South African pharmaceutical industry and consider the impact of the amendments to existing legislation, on stakeholders, specifically with regard to the banning of sampling, the use of generic medication and the removal of incentives. Finally, a Marketing Code for the pharmaceutical industry will be compiled.

1.10 METHODOLOGY

Secondary data will be used to acquire information about all the stakeholders in the pharmaceutical industry in South Africa. Induction will also be used, as generalizations will be made from specific observations to draw conclusions (Babbie 1998:66).

1.10.1 Design Type

This study is exploratory in nature as an attempt will be made to understand the impact of legislative changes on stakeholders. It is explanatory as it will try to explain the forces that led to the legislative changes and the reason for the selection of the factors listed in the amendments. The objective of the exploration will be to expand our understanding of the impact of these amendments on stakeholders. One key to this understanding would be to look at the way that other countries have addressed the need for the regulation of the marketing activities of pharmaceutical companies. These lessons learned from other countries with respect to a Marketing Code can be incorporated in the design and implementation of such a code in SA.

The methodology to be adopted is one of qualitative comparison. No attempt will be made to quantify benefits, costs or risks, as the objective is to uncover and understand information regarding changes in legislation and its impact on stakeholders. This method is validated by Ghauri, Gronhaug and Kristianslung (1995:85) in their statement that "It is generally accepted that for inductive and explorative research, qualitative methods are most useful, as they lead to hypothesis building and explanations".

The case study methodology will be implemented, as it allows for the study of the impact of legislative changes on stakeholders. This method is supported by Leedy and Ormrod (2001:157) who suggest that a case study methodology is applicable in poorly understood situations where the explicit purpose is to explore in greater depth the issues. The validity of this method is confirmed by Yin (I Chetty, 1996:73) who defines a case study as an "empirical enquiry that: investigates a contemporary phenomenon within its real life context; when the boundaries between phenomenon and context are not clearly evident; and in which multiple sources of evidence are

used". Chetty (1996:73) also states that case studies are appropriate for explanatory and exploratory research.

1.10.2 Data Collection and Sources

Patton (1999) suggests that the use of varied methods and sources of data collection increases the reliability and validity of a study. Sources of data for a case study methodology can include amongst others: interviews, textbooks, journal articles and Internet web sites (Leedy and Ormrod, 2001:157).

The data collection for this study included: semi-structured interviews with five psychiatrists from the KZN branch of SASOP (Drs V Agambaram, K Domingo, C Maud, J Krystofiak and Dr P Miseer); informal discussions with members of the National Executive Committee of SASOP (Dr Eugene Allers – President of SASOP based in Pretoria, Professor Margaret Nair- Editor of Headline, Dr Mohamed Salduker- Public Relations Officer);informal discussions with PPSA directors (Dr Franco Colin, based in Gauteng and Dr Francois Daubenton, based in Cape Town) unstructured interviews with representatives of pharmaceutical companies involved in the antidepressant market (Anne Bennet – Pfizer SA, Nicole Wortmann - Lilly SA and Cheryl Prior- Lundbeck SA) and unstructured telephonic interviews with product and sales managers of pharmaceutical companies involved in the antidepressant market (Akbar Wallele, based in Gauteng – Pfizer SA, Elaine Milne, based in Gauteng- Lundbeck SA) and informal discussions with Ben Christen, based in Gauteng - Managing Director, Lundbeck SA and Dr Frans Korb, based in Vienna, - Medical Director, Lilly SA, CNS Product Division. Journal and Internet articles, textbooks, brochures relevant to the subject matter were also analyzed. The data was collected and analyzed concurrently and was examined, compared and used for analysis.

1.11 EVALUATION OF THE STUDY

Internal validity, external validity, reliability and objectivity are criteria that can be used to evaluate qualitative research. Internal validity considers the degree to which a study correctly assesses the phenomenon and external validity is the degree to which the findings can be generalized. The degree to which findings are considered free

from bias, assists in a study's objectivity. Multiple data sources and methods providing corroborating evidence, increases internal validity and credibility (Devers:1999), which is also increased by subject review. The researcher will adopt a clear data analysis process to increase dependability and reliability and triangulation and sceptical peer review to increase conformability and objectivity.

1.11.1 Credibility

Credibility is determined by three elements (Patton:1999). These include:

- Credibility of the researcher, which is reliant on the experience and status of the researcher
- The responsiveness of the researcher to the data and the capacity for impartiality. Corroborating evidence from a variety of sources will reduce the researcher's bias in this study.
- The validity, reliability and transferability of data is important, so techniques and methods to ensure a high quality of data, will be used.

1.11.2 Validity

The validity of findings can be supported by triangulation of multiple data sources in search of a common theme (Leedy and Ormrod, 2001:106). A detailed description of the context of the observations will be made to increase the external validity of findings.

1.11.3 Reliability

Reliability is the degree to which findings can be replicated. Consistency of results is fundamental to determining reliability in a study (Babbie, 1998:129), therefore the researcher will ensure completeness and accuracy of interviews and observations. Sceptical peer review will be used to increase dependability and reliability. Triangulation will be used in this study to increase the reliability of findings (Patton:1999).

1.11.4 Transferability

According to Devers (1999), the similarity of contexts is central to the transferability of findings. In this study, there will be a clear description of the study context and the investigator's role so that transferability is feasible.

1.11.5 Triangulation

Qualitative research is enhanced by triangulation as "multiple methods of data collection and analysis provide more grist for the research mill" (Patton:1999) and is useful to understand differences in findings as it considers reasonable explanations for differences. The reliability of findings is dependent on the consistency of the results, which triangulation will facilitate.

Source triangulation is the examination of the consistency of different data sources by comparing and cross-checking the consistency of information collected at different times and by different means within qualitative methods. Observational data will be compared to interview data and different perspectives of different points of view will be considered for consistency over a time period. Multiple sources or perspectives to interpret the same data, is used in perspective triangulation, the objective of which is to determine how findings are affected by different assumptions. In this study source triangulation and perspective triangulation will be used to determine the consistency of results.

1.12 LIMITATIONS OF THE STUDY

The following factors were considered as limitations of this study:

- The pharmaceutical sector and its interaction with its customer base is a dynamic situation, so it was not possible to analyze all aspects.
- The study was done only amongst stakeholders in the antidepressant market An assumption was made that the findings represents a fair reflection of the issues in the industry as a whole.
- Selectivity in the sampling of people for interviews and selectivity in document sampling may have occurred.
- Due to time constraints, relevant information about the changes that were occurring may have been ignored in the short time period of sampling.
- The case study analysis has focused mainly on three of the stakeholders, the pharmaceutical companies, service providers and government in its strategic analysis, due to the vastness of the analysis that would have been required, should all stakeholders have been evaluated.

1.13 CONCLUSION

Chapter One has provided an overview of the issues relevant to the legislative changes in the Medicines and Related Substances Amendment Act. It has also identified all stakeholders in the industry. Government's role in legislation has been highlighted and the impact on pharmaceutical companies and psychiatrists in private practice considered. The research objectives and methodology, including limitations to the study were also described. Chapter Two focuses on strategic theory and undertakes a strategic analysis of the pharmaceutical industry, with a focus on three stakeholders, the SA government, pharmaceutical companies in the antidepressant market and psychiatrists in private practice.

CHAPTER TWO: STRATEGIC THEORY AND STRATEGIC ANALYSIS

2.1 INTRODUCTION

This chapter outlines the strategic theory that formed the framework for the analysis in this case study. The principles of strategic theory will be described, including details of the environmental analysis and strategic tools used in the analytic process. The chapter ends with a focus on the analysis of strategic change within the pharmaceutical industry. Even though, there are several stakeholders in the industry, the strategic analysis was weighted in favour of the pharmaceutical companies for the purpose of this case study. Brief comment is also made with regard to the role of government and the service providers. This was done due to the vastness of the subject matter, time constraints and for the purposes of clarity in the strategic analytic process.

Before the present decade, the pharmaceutical industry generated attractive returns by investing heavily in the discovery and development of new drugs and by vigorous sales to a growing market of medical professionals. Patent protection decreased the level of price competition and health insurance made consumers relatively insensitive to price. Brands were chosen almost entirely at the discretion of practitioners, whose preferences were greatly influenced by the marketing activities and sales coverage of drug companies.

In the 1990's the emergence of managed health care in the global pharmaceutical arena, threatened to 'end the party'. The managed care model bypassed the independence of the service provider by creating a process whereby services were rendered in return for a fixed fee via companies that contracted directly with employees. This business model had to change in the US, when pharmacy benefits-management companies, which helped large corporations manage the cost of their pharmacy benefits programs, began to swing the choice of products from branded products to low cost alternatives, in exchange for incentives. These companies proceeded to capture part of the profits of the industry and the managed-care model did not manage to alleviate the burden on medical insurance companies and consumers.

There was also a serious threat to the ethical practice of medicine as the managed care model worked via a system authorisation for services by case workers, who were clerks with no medical training. This compromised patient care as doctors were allowed limited treatment options but were still held accountable for the outcome. This day has now arrived at the door of the pharmaceutical industry in the developing world as managed care companies looked for new markets as the concept had flopped miserably in the US market. SA was infiltrated in the late 90's after the process of democratic change, when the country was in a state of flux. Service providers and pharmaceutical companies have battled to keep pace with the changing face of medical practice in South Africa. Management of strategic change is now vital for the pharmaceutical industry in this country, which has largely been reactive to the process, as a survival measure. For growth to occur in the industry, a proactive strategic approach needs to develop amongst all major role players.

Another major challenge facing pharmaceutical companies worldwide is that patents only last for 20 years. After patenting new products it can take a decade or longer for appropriate testing and trials to be conducted before the product gains FDA approval and is ready for marketing. The process of discovering, testing and developing a new drug is complex, costly and time-consuming. Pharmaceutical companies spend a huge proportion of their turnover on research and development, as the race to develop and patent new products

In order to analyze the trends within the SA pharmaceutical industry, SA companies with a presence in the antidepressant market, Lilly SA and competitors, Pfizer SA and Lundbeck SA, will primarily be used as examples. To facilitate the discussion, a brief background to the companies is useful.

2.1.1 Pharmaceutical companies in the antidepressant market

Lilly (SA) is a pharmaceutical company that is a subsidiary of Eli Lilly, a global player in the industry. Headquartered in Indianapolis, Indiana, USA, since 1876, Lilly has a portfolio of best-in-class pharmaceutical products for depression, psychosis, cancer, osteoporosis and diabetes products. Eli Lilly products have been available in South Africa since 1937 initially through Johnson & Johnson, who were appointed

sole distributors of Lilly products. In 1963 a plant was built to manufacture Lilly products locally. The South African manufacturing operations were closed in 1998 as a result of a global review of manufacturing capacity and production costs and from then on the company's research and development (R & D) has been coordinated from Indianapolis. A large percentage of Lilly's global clinical research is still carried out in South Africa (Internet 16).

Lilly SA is divided between South Africa and sub-Saharan Africa, the latter operating out of Kenya and reporting to the South African office. Lilly SA's accounts are consolidated with those of head office. Lilly SA turns over approximately R280 million per year. The parent company turned over $11.5 billion in 2001. Lilly South Africa spends approximately R120 million per annum locally in research and development through clinical trials. In addition to Prozac, top sellers to date include Zyprexa, Evista, Gemzar and Lorabid (Internet 16).

Prozac has been Lilly's best selling product for a number of years. Like the rest of the pharmaceutical industry, Lilly SA faces challenges of products coming off patent. Prozac lost patent protection in the United States this past year. The company is now tasked with ensuring that it maintains turnover and business, in spite of losing its biggest revenue generator ever. Not many pharmaceutical companies would have survived losing a blockbuster like Prozac. However, Lilly's new product pipeline is one of the richest in the pharmaceutical industry, with a number of potential blockbuster products to be released in the next seven to eight years. The challenge for Lilly South Africa has been to provide healthcare to a shrinking private sector and an emerging middle class market (Internet 16).

The US-based Lilly Foundation has been extended to South Africa. The Foundation's premise is that the cure for many diseases centers around education. The Foundation also provides education bursaries and access to free TB medication around the world. One of the first projects they have concentrated on in South Africa is diabetes education (Internet 16).

Pfizer South Africa is a subsidiary of the world market leader in pharmaceuticals, Pfizer Laboratories. Its' latest merger with Pharmacia made it the first in every major

world market. The Pfizer brand now represents more than 120,000 men and women. The company has the world's largest privately funded biomedical research group, visible around the world, investing more than $100 million every week discovering and developing high-value medicines. Tiger Brands' subsidiary Adcock Ingram acquired the Parke-Med generic business from Pfizer South Africa this year. The sale includes registrations and trademarks for a number of generic pharmaceuticals (Internet 17).

Pfizer and the South African Ministry of Health have worked very hard together to initiate the Diflucan Partnership Programme. Pfizer expects to contribute more than R375 million ($50 million) of Diflucan over the course of the programme. Pfizer is also committed to initiating discussions with other members of South African Development Community (SADC) with a view to the possible expansion of the programme within the SADC region. Pfizer has been very active and a dedicated contributor to developmental initiatives and health care in South Africa and throughout the world. As a founding member of Medical Education for South African Blacks (MESAB), the company provided the organization's first grant as well as ongoing financial support over the past 15 years. Pfizer also works with the Programme for Technological Careers (PROTEC) to improve mathematics and science education and teacher training in disadvantaged community high schools (Internet 17).

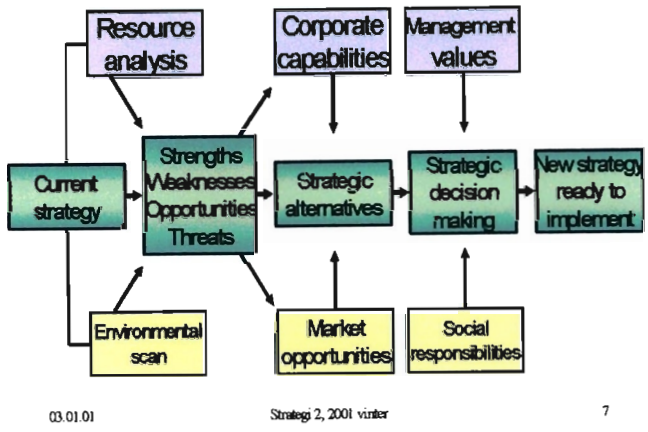
Lundbeck's South African headquarters are located in Randburg, Lundbeck South Africa has around 40 employees, of which half work at the headquarters while the other half are sales staff located throughout the country. Ten years after Lundbeck set up shop in South Africa in 1984, it launched Cipramil®, which has now led the antidepressant market in South Africa since 1997 (Internet 18).

2.1.2 Definitions of Strategy

Strategy is concerned with the long-term direction and development of an entity and is influenced by the values and expectations of all stakeholders. Strategic decisions are made at a number of levels in any industry and are about a search for strategic 'fit', in which ways could be found to match the activities within companies, to an

external environment. This concept is well illustrated in Andrew's strategy model depicted in Figure 2.1.

Figure 2.1: Andrews Strategy Model



Source: Internet 9

The model depicts four components of strategy:

- Market opportunity which involves the identification of opportunities and assessment of risk
- Corporate competence and resources, the assessment of a company's capacity to capitalize on opportunities and manage risk
- Personal values and aspirations that influence the choices of executives
- Stakeholder responsibility which incorporates the consideration of all stakeholders in strategic decisions

Strategy can thus achieve advantages through its configuration of resources within a changing environment, to meet the needs of a market and fulfil stakeholder expectations. It may be viewed as a perspective that is shared by individuals united by common thinking or behaviour that attempts to match organizational strengths and weaknesses of companies and the environmental opportunities and threats (Johnson and Scholes, 1999:10).

It has been suggested that it is imperative to understand the turbulence in respective environments in order to select a model for the development of strategic direction. In

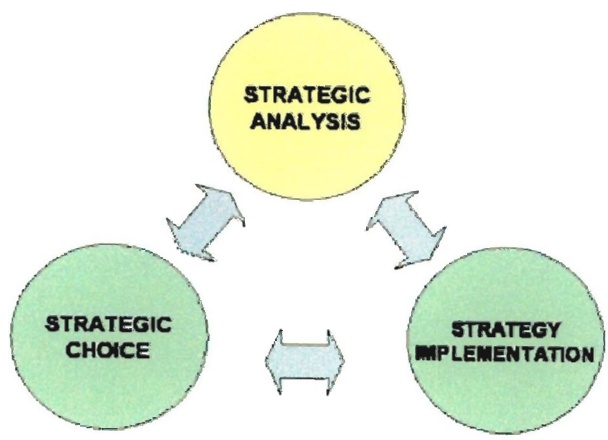
fact, Stacey (1993) advocated the creation of a climate of chaos, where existing perceptions are challenged so that there can emerge innovative strategic direction.

2.1.3 Strategic Management

The strategic management process is one where a strategic vision is formed and objectives are set, before crafting, implementing and executing occurs. Corrective adjustments in the vision, objectives and strategy are then initiated over time (Thompson and Strickland, 2001). Strategic management has three elements: strategic analysis, strategic choice and strategic implementation. Strategic analysis is the process of trying to understand the strategic position of a company in terms of its external environment, internal resources and competences and the expectations and influences of stakeholders. Strategic choice involves understanding the underlying bases guiding future strategy and is a process whereby strategic options are generated for evaluation and selection. Strategic implementation is concerned with the translation of strategy into activity through structure and design, resource planning and the management of strategic change (Internet 9).

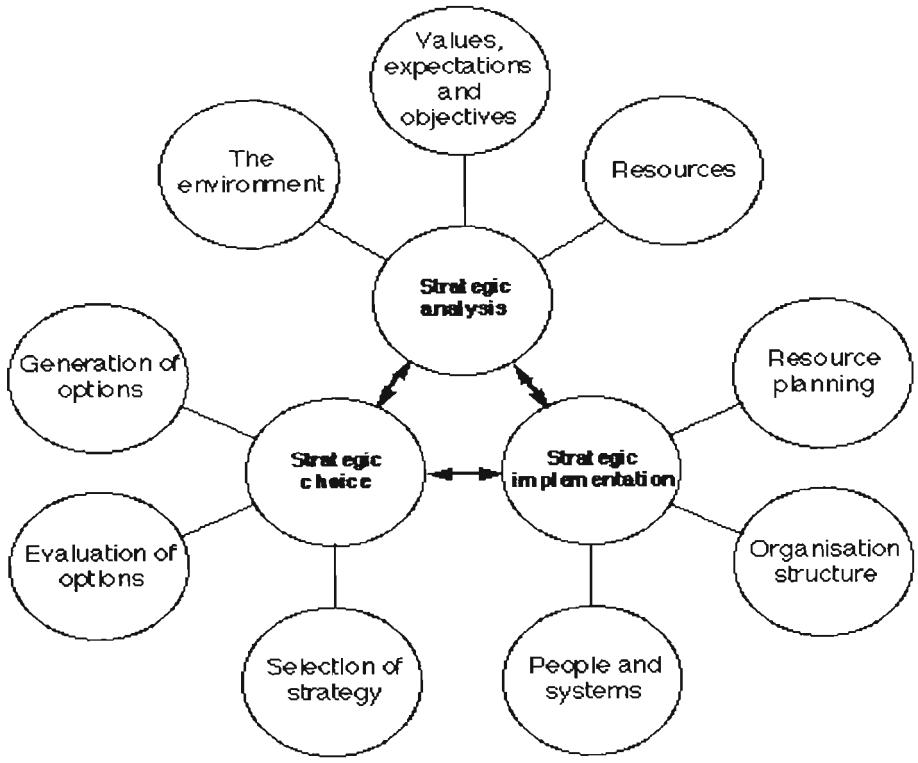
These three main components are depicted in Figure 2.2 and Figure 2.3 summarises all the elements of the process of strategic management.

Figure 2.2 : Components of the Strategic Management Process



Source: Internet 9

Figure 2.3: A summary model of the elements of strategic management



Source: Johnson, G and Scholes, K. (1984)

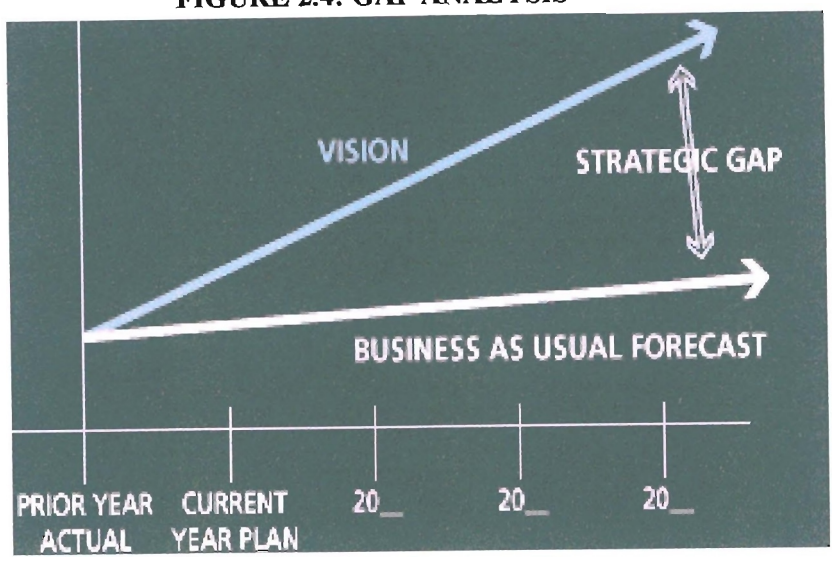
Different contexts thus have relevance for the process of strategic management. An environment-led 'fit' strategic management process achieves competitive advantage by 'correct' positioning and product differentiation that is directed by market need and risk reduction through specific portfolio establishment (Internet 9). For instance, small businesses are likely to operate in a single market, with a limited range of products and services whereas multinational corporations (MNC's) face key strategic issues that are substantially different. MNC's usually operate with diversity in terms of products and geographical markets. An option available to MNC's because of their capacity is to opt for resource-led 'stretch' where, the 'rules of the game' are changed by the MNC and differentiation is based on competences suited to creating market need (Johnson & Scholes: 1999).

2.1.4 Strategic Planning

Lynch (2000:780), considered strategic planning an essential process for growth of any industry even though it may not always be feasible, especially in situations where

there is too much bureaucracy and rigidity, poor directional behaviour from management and political difficulties (Lynch, 2000: 782). This process usually focuses on attempting to fill the gap between reality and the company's vision.

FIGURE 2.4: GAP ANALYSIS



Source : Internet 9

Gap analysis, illustrated in Figure 2.4 above, is an important part of the process of setting strategic direction. It considers where an organisation is going versus where they'd rather be and is a useful strategic tool as there is usually a gap between the two points. Analyzing this gap, and developing measurable, time-bounded plans to fill it forms the basis of strategic planning. This process assists in the definition of strategic alternatives and creates the basis for strategic implementation. As environments become more unpredictable, the need for innovation, flexibility and diversity in an industry does increase.

When one considers the pharmaceutical industry in South Africa, there is a significant difference between the current market and that which existed five years ago. There are positive and negative aspects to this. The shift to a democratic government increased the pool of the population that constitute the private sector. Hence, the size of the potential market for pharmaceutical companies has increased substantially. At the same time, there have been widespread policy shifts that have directly targeted profit margins and the way the companies do business. This has impacted on the costs of

achieving the same market share. Most of the subsidiaries of international companies are faced with the reality that for them to achieve their goal to satisfy shareholder expectations, strategic planning is imperative. Several measures in the short-term to reduce the gap between where companies find themselves now and where they would like to be, can be taken. These include rationalisation of staff, re-allocation of budgets, divesting of certain products in the portfolio and development of others in line with the market, investments in social responsibility programs, and collaboration within the industry.

2.2 ENVIRONMENTAL ANALYSIS

Environment encompasses every aspect external to an organization: not only the economic and political circumstances but competitors, customers and suppliers, who vary in being aggressive to a greater or lesser degree (Lynch 2000:9). Environmental analysis is a process whereby opportunities and threats in the environment are identified to influence strategic direction and to develop processes whereby sustainable competitive advantage may be maintained (Lynch, 2000:107). Where the environment is increasingly uncertain and central control remains possible, a more incremental approach to strategy development is usually the sensible route (Internet 9). There is no doubt that the industry is in a state of flux with drastic policy changes, increasing production costs, due to a world-side economic recession and increasing pressure from the World Bank and the World Health Organisation (WHO) to address the imbalances in health care delivery globally.

The marketing environment surrounds and impacts upon the organization. There are three key perspectives on the marketing environment, namely the 'macro-environment,' the 'micro-environment' and the 'internal environment' as depicted in Figure 2.5.

Figure 2.5: The Marketing Environment

Source: www.marketingteacher.com

2.2.1 The micro-environment

This environment influences the organization directly. It includes suppliers that deal directly or indirectly, consumers and customers, and other local stakeholders. Micro tends to suggest small, but this can be misleading. In this context, micro describes the relationship between firms and the driving forces that control this relationship. It is a more local relationship, and companies exercise a degree of influence.

2.2.1 The macro-environment

This includes all factors that can influence and organization, but that are out of their direct control. A company does not generally influence any laws, although it is accepted that they could lobby or be part of a trade organization. It is continuously changing, and the company needs to be flexible to adapt. There may be aggressive competition and rivalry in a market. Globalization means that there is always the threat of substitute products and new entrants. The wider environment is also ever changing, and the marketer needs to compensate for changes in culture, politics, economics and technology (Internet 15).

2.2.3 Assessing the nature of the environment

Evaluating the nature of an environment is a useful way of providing an initial view of the influences within an environment. Historical analysis and forecasting are usually sufficient in static conditions whereas scenario planning is more useful in more dynamic conditions (Johnson and Scholes, 1999:141).

2.2.3.1 Assessing the dynamics of the environment

Table 2.1: Analyzing environmental turbulence

Environmental Turbulence	*Repetitive*	*Expanding*	*Changing*	*Discontinuous*	*Surprising*
A.*Complexity*	National	National	Regional Techno-logical	Regional Socio-political	Global
B.*Familiarity of events*	Familiar	Extrapolable		Discontinous	Discontinous
C.*Rapidity of change*	Slower than response		Comparable to response		Faster than response
D.*Visibility of future*	Recurring	Forecastable	Predictable	Partially predicatable	Unpredictable surprises
Turbulence	1	2	3	4	5
Level *Low*					*High*

Source : Modified from Lynch (2000:108)

When considering the strategic environment, attention needs to be directed to the nature and strength of the forces driving strategic change i.e. the dynamics of the environment which are depicted in Table 2.1. The nature of the environment influences the way an organization is structured to cope with such changes and can be assessed using two main measures:

- Changeability – the degree to which the environment is likely to change. In the table, A+B = changeability. Changeability comprises complexity, the degree to which the environment is affected by social and political complications and novelty, the degree to which new situations are presented.
- Predictability – the degree with which changes can be predicted. In the table,

C + D = predictability which has two components: rate of change of the environment and visibility of the future in terms of availability and usefulness of the information used to predict the future.

It is possible then to build a spectrum that categorizes the environment and provides a rating for its degree of turbulence as seen in the above table. When turbulence is low, it is possible to predict the future with certainty. When one considers the SA situation, the pharmaceutical industry has been functioning since 1997 in a fairly turbulent environment, where there was a lot of 'political speak' about the coming changes and constant negotiations around political agendas. This legislation has featured prominently in the international press which has not assisted the stability of the local industry. Employees within the industry like medical representatives have had to live with uncertainty also in the wake of mergers and acquisitions, which were taking place with parent companies in the international arena. Now that the legislation has been gazetted, there is almost a sense of relief that the waiting is over. There is acknowledgement that the rules have changed, even though acceptance of the changes is still filtering through the system. The future still remains uncertain as the rate change has been unpredictable and the nature of change extremely complex.

2.2.3.2 Scenario-based analysis

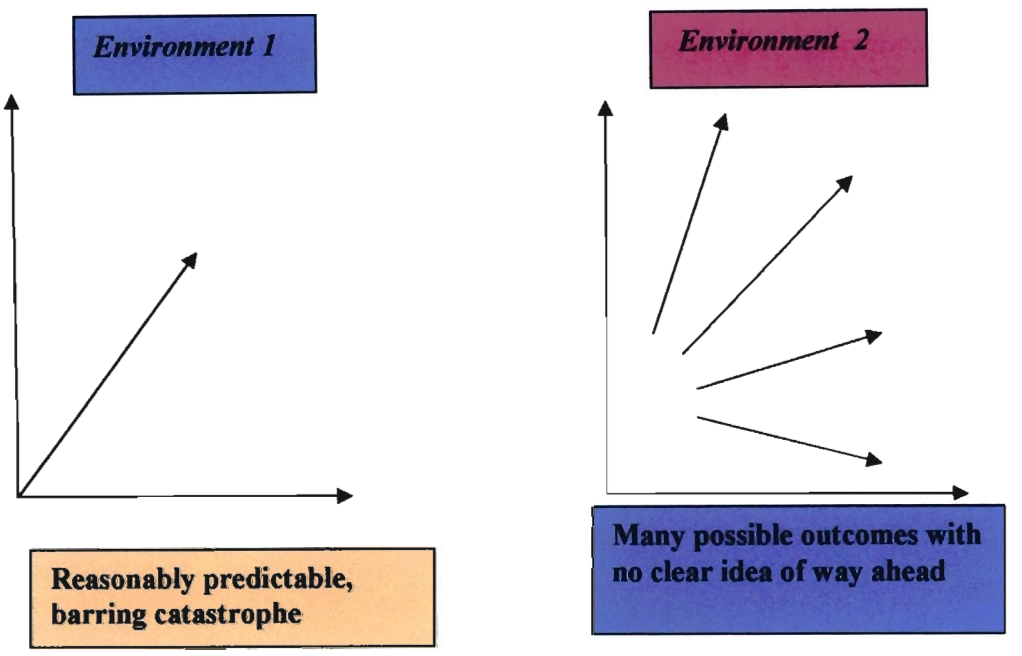
A scenario is a model of a possible future environment, created for the purpose of investigating the strategic implication of future situations. A scenario-based analysis is not about predicting the future but about taking different situations with alternative starting points and exploring a set of possibilities. A combination of events is gathered together into a scenario and the combination is explored for strategic significance. The starting point is normally an unusual viewpoint, from which a qualitative description of a group of possible events is developed or a narrative listed that shows how events unfold. The outcomes are then explored building two scenarios that can be differentiated into 'most optimistic' and 'worst-case scenario'. The uncertainty is included as a variable and consequences are explored. Scenario planning is useful if it leads to new strategic thinking.

When one considers the situation that drug companies in South Africa find themselves in, this is possible a good place to start for the company that plans to stay and sit out the changing market. It is evident that there is no precedent for the rapidity of the

changes that occurred in SA and the relatively unilateral way in which decisions were made. There was also a sense of disbelief when the giant pharmaceuticals withdrew their court action against the government as many in the industry in SA had believed that this was not a case the industry could have lost. The way forward is for companies to construct the best and worst possible scenarios for their management teams in workshops so that innovative strategic planning can occur in the immediate future.

2.2.3.3 Analyzing environmental uncertainty

Figure 2.6 Coping with different levels of environmental uncertainty



Source: Modified from Lynch (2000: 897)

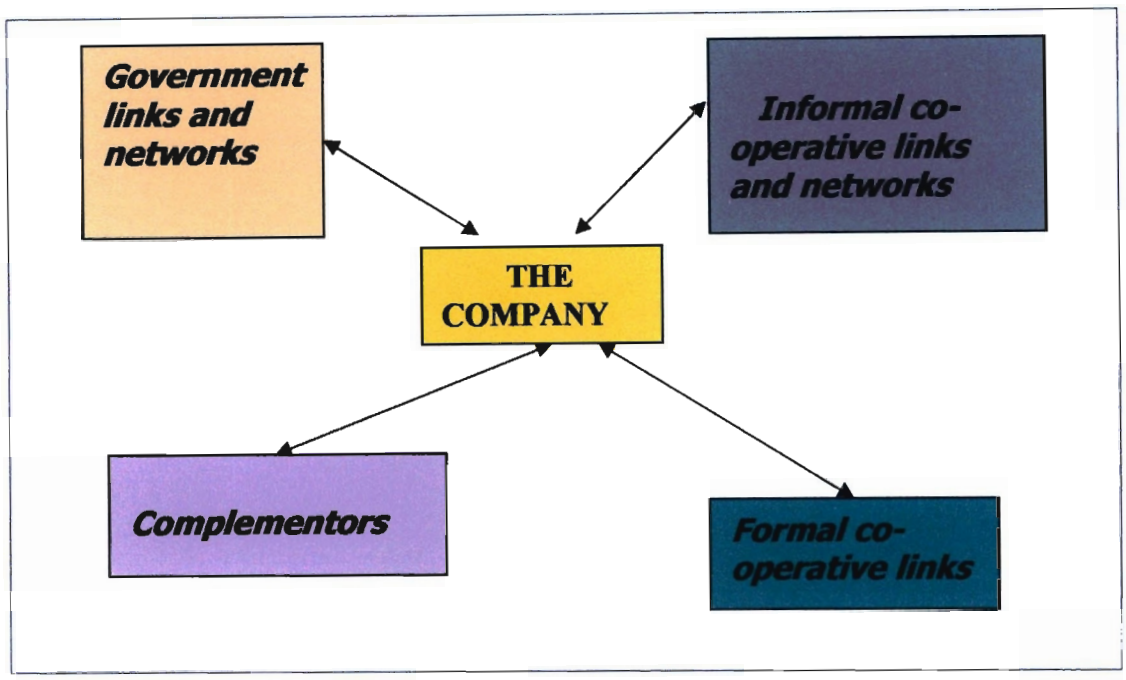
Pharmaceutical companies have had to face an uncertain environment since 1997. The reality is that there are more than one ways to respond to a situation of rapid change. As is depicted in Figure 2.6, if the environment is predictable, the dynamics of the environment can be managed more easily. If the environmental uncertainty is totally unpredictable, there are several possibilities of how to react. Often no clear way ahead can be seen as the possible outcomes are too many. Even if drug companies understood the nature of the change, they may still not be able to act on it. Some of the reasons for this may include: a distorted perception of change and the

environment, failed creative responses from its management team, political deadlocks with government over key issues and dulled motivation from staff who have been kept in a state of limbo for too long.

2.2.3.4 Analyzing the Co-operative environment

There are several key role players in the SA pharmaceutical industry. Despite the uncertainty, there are positive aspects that are core issues in the environment. As well as competing with rivals, companies could embark on a course of co-operation with the other stakeholders. Four possibilities of co-operation exist as seen in Figure 2.7:

Figure 2.7: THE FOUR LINKS MODEL: ANALYZING CO-OPERATION



Source: Modified from Lynch (2000 : 133)

The objective of this analysis is to establish the strength and nature of the co-operation that exists between a drug company and its environment. Informal co-operative links and networks occur when companies link together for a mutual or common purpose, and there is no legally binding contractual relationship. In this case, it is the strengths or weaknesses of the relationship that matters. For Lilly, Pfizer and Lundbeck, as some of the major players in the industry with similar product portfolios, the collaborative route has a lot of plus factors, as the combined strength would have greater influence with government and the medical aid industry.

Formal co-operative linkages can occur in the form of alliances and joint shareholdings, marketing agreements and joint ventures. The strengths and weaknesses of such linkages are assessed in terms of their depth, longevity and degree of mutual trust. There have been several such mergers and acquisitions of parent companies and there are joint marketing agreements between companies, especially where there is a perceived lack of expertise.

Complementors are those companies whose products add more value to the products of other companies than they would derive from holding their own products in a product portfolio themselves. In South Africa, with our restricted branded product range, such a situation does not exist. Finally, government links and networks are vital to the process of advancement of the interests of drug companies. There are huge tax and legal matters that government has direct influence over. Some drug companies have cultivated this relationship through lobbying the combined interests of the industry and the consumer. A lot of the collaboration occurs behind the scenes however, in deals struck between governments of host countries as part of political relationships.

2.2.4 Auditing Environmental Influences

Environmental forces vary over time and there must be an awareness of their changing impact. Two common tools, namely the PEST analysis and Porter's Diamond are used for auditing environmental influences.

2.2.4.1 Political, Economic, Social, Technological (PEST) Analysis

Appendix Two illustrates some of the factors that are relevant when doing a PEST analysis. Factors that influence an industry should be prioritized as an unlimited number of factors can impact upon strategy. In climates where there is rapid change or a period of uncertainty, forecasting of future trends with an acceptable level of accuracy to impact on strategic direction is not always feasible. Scenario planning techniques, which deal with high levels of uncertainty in important macro-environmental variables, may sometimes be a more relevant option.

In the present context that the industry finds itself in, a PEST analysis reveals that there is political interference in the industry world-wide, in the form of policy changes, regional agreements, challenges to existing trade agreements, trade-offs between governments for political agendas and very real threats to intellectual property rights. With increasing political stability in some areas of the developing world, focus is now shifting to service delivery and there is an expectation that is being created that MNC's will come to the party. There is a sentiment world-wide that suggests that the major companies have been profit-driven at the expense of ethical business practice and there are increasing calls to reduce costs of branded products. This could seriously impact on the future development of the industry and the development of the 'product pipeline', which is essential for any company's survival in this sector.

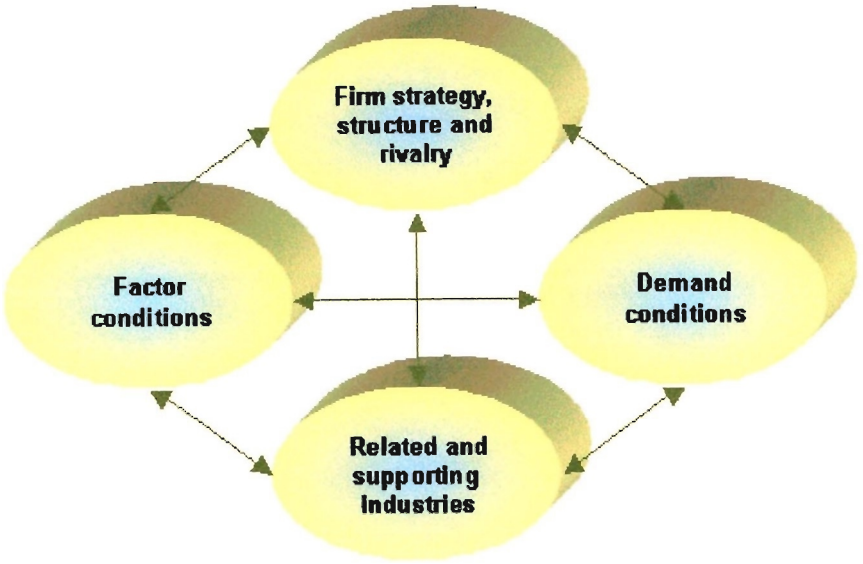
The technological advances that have been possible, with new product development and time-to-market once a viable molecular product is discovered have astounded other industries. This is now under threat and even collaboration attempts between MNC's and private-public sector partnerships have not managed to stem the tide of anti-drug company sentiment that threatens R& D facilities internationally. The biggest factor influencing the drug prices of branded products is the single exit price policy of most companies. With fluctuating exchange rates internationally, in the face of a strong dollar and pound, there has been little room to manouver for actuaries in determining international prices. If the policy is changed, it is possible then for consumers in the host country to demand the right to have the medication at the same price that it is made available internationally, which would drive the prices down anyway. Lower prices equal lower profits equal lower R& D expenditure and investment in social responsibility programs.

2.2.4.2 Porter's Diamond

Porter's Diamond is a model that allows the analysis of competitiveness in a nation. It suggests that there are inherent reasons why some industries within nations are more competitive than others. Specific factor conditions help in the explanation of the basis of advantage at a national level. This can on to yield more advanced factors of competition. In the case of the pharmaceutical industry, for instance, where legislative

changes encourage the use of generic alternatives, there should be a greater impetus towards investing in that sector of the industry. Porter's Diamond is illustrated in Figure 2.8.

Figure 2.8: Porter's Diamond



Source: Internet 9

It is very important in any industry that globalisation drivers are identified. In pharmaceutical markets, market convergence is often a low driver as there can be a wide variation in brand names used for products in different countries especially in over-the-counter (OTC) medications. Differences also exist between markets for ethical (prescription) pharmaceuticals. This is because medical treatment plans and programs differ across the world. Cost advantages in South Africa are not always easily attainable, as the marketing budgets of most role players are geared for national brand names, leaving little scope for global economies of scale in the OTC market. Governments are also adopting policies of cost containment in health care, especially in the ethical market. Although this factor and the harmonisation of clinical standards has facilitated a globalised approach, in South Africa, other factors also impact on this arena. There are legislative standards for instance with OTC and ethical pharmaceuticals, like the maximum allowed dosage, that vary greatly from country to country. This incompatibility means that there is little scope for globalisation. There is

competitive pressure on MNC's in the pharmaceutical sector to develop globally but because of differences in legislation governing the use of pharmaceuticals, competition is sometimes better at the local than global level.

According to Porter the domestic rivalry and the search for competitive advantage within a nation can help provide organizations with bases for achieving advantage on a more global scale. At a national level, Porter's Diamond can be employed by government to consider the policies that they should follow to encourage the competitive advantage of their industry. Domestic characteristics of competition yield advantages on a wider basis, therefore governments should encourage competition at home rather than be protective regarding overseas competition. Governments can also act to foster advantage by ensuring high expectations of product performance, safety or environmental standards and encouraging vertical co-operation between suppliers and buyers on a domestic level.

2.2.4.3 Analyzing Stakeholder Reactions

The importance of understanding the political context for strategic change cannot be emphasised enough. Stakeholder mapping is a way of analysing and prioritising the 'political agenda' for an organisation and is a valuable tool in assessing the likely reactions of stakeholders to new strategies and the company's ability to manage these reactions. The key issue with regard to stakeholders is that the company needs to take them into consideration when formulating objectives. The company needs to address which stakeholders have priority by analyzing stakeholder. This involves:

- Identifying major stakeholders
- Establishing their interests and claims on the company, especially as new strategies develop
- Determining the degree of power each group holds through its ability to force or influence change as new strategies are developed
- Developing objectives and strategy, prioritized to minimize power clashes between stakeholders
- Diverting trouble before it starts, possibly by negotiating with key groups
- Identifying the sanctions available and applying them to ensure that either the company's purpose is met or a compromise is reached

Table 2.2 considers stakeholders and their expectations.

Table 2.2: Stakeholders and their expectations

STAKEHOLDER	EXPECTATIONS	
	PRIMARY	**SECONDARY**
Owners	Financial return	Added value
Employees	Salaries and wages	Work satisfaction
Customers	Supply of products	Quality
Creditors	Good record	Payment on time
Suppliers	Payment	Relationship
Community	Safety	Contribution
Government	Compliance	Competitiveness

Source: Lynch (2000:521)

Game theory, which is an approach to decision analysis, is one way of dealing with stakeholder issues and how they impact on a company. This theory assumes that groups are likely to react to the moves each other makes. It helps analyze dynamic and sequential decisions at the tactical level. The present stand-off between government and the industry is an ideal situation in principle where game theory can be utilized. Key applicable areas that could be explored with this strategy include:

- New product introduction – At present government's policy at the MCC is that generic drugs at preference for registration purposes and patent drugs are on a waiting list that is delaying product launches in this country by up to 2 years after launches internationally.
- Licensing versus production – Government desires to see FDI and prefers that drug companies invest in manufacturing infrastructure rather than benefit from licensing opportunities in this country with reduced commitment.
- Pricing – this area has been characterised by tactical moves by both parties. Government feels that drug companies' prices are too high and out of range of the majority of consumers in this country. The drug companies feel that as originators, they have the right to determine a fair market price, without government intervention

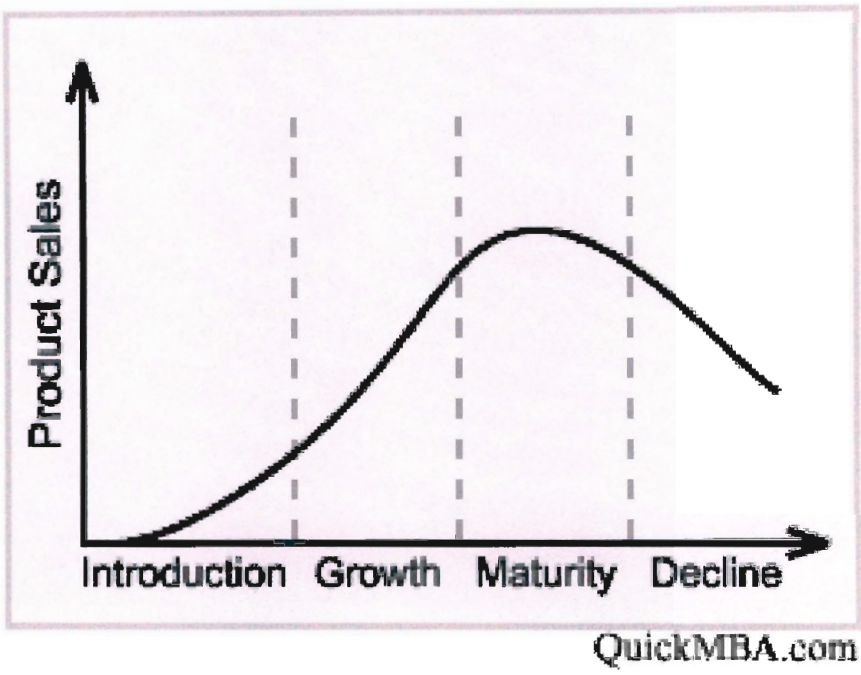
- R & D – drug companies are investing in R& D facilities internationally but are using SA patients as subjects. Government has raised concerns that this represents an exploitation of developing countries
- Advertising- government has embarked on a legislative course to tackle this area but the reality is that advertising is essential to market growth and there is no reason why ethical advertising cannot be permitted as part of consumer education initiatives
- Regulation- this is clear as government is attempting to regulate the industry and the industry is investing time and energy in attempting to find ways around the restrictions to service its customer base

Successful strategy therefore does not just depend on a firm's position in the industry, its capabilities or what have you. It also depends on how others react to your moves and how others think you will react to theirs. By fully understanding this dynamic with government, the industry will find win-win strategies that will have a better outcome in the long-term.

2.2.5 Industry Life Cycle

According to Porter in (Lynch, 2000:112), there are four evolutionary phases of growth in an industry: introduction, growth, maturity and decline as depicted in Figure 2.9. In the development of strategy, two consequences of the industry cycle have a significant impact on industries. One is the advantage of early entry. There is substantial empirical evidence that the first company into a market has the most substantial strategic advantage. The second reality is that fragmentation occurs as a market matures. The cyclicality of a market is also relevant as it has a definite impact on market demand. Economic or political cyclical conditions over which companies have little control are a reality. For instance a decline in an economy can influence cyclicality. In mature markets, as is expected, demand for a product usually slows down, except where a product wears out, and there is replacement demand. When the economy is low, purchases can be temporarily delayed thereby reducing demand.

Figure 2.9: Industry Lifecycle Model



Source: Internet 11

Table 2. 3: Lifecycle Model

	Introduction	Growth	Shakeout	Maturity	Decline
Users/Buyers	Few: trial of early adopters	Growing Adopters: trial of product or service	Growing selectivity of purchase	Saturation of users Repeat purchase reliance	Drop-off in usage
Competitive Conditions		Entry of competitors	May be many competitors	Fight to maintain share	Exit of some competitors
		Attempt to achieve trial	Likely price cutting for volume	Difficulties in taking or gaining share	Selective Distribution
		Fight for share	Shakeout of weakest competitors	Emphasis on efficiency/low cost	
		Undifferentiated product/service			

Source: Johnson and Scholes, 1999

Table 2.2 illustrates buyer behaviour and competitive conditions for the various lifecycle stages, which is significant in understanding the competitive behaviour of role players in a market (Johnson and Scholes, 1999:121). The global pharmaceutical industry for ethical and generic medication is still in a growth phase. There is consistent fight for market share in developed markets. Barriers to entry in developing markets is low, therefore the market remains fiercely competitive. There is also increasing demand for new product development, especially in the developed world.

2.2.6 Analyzing the role of government

At government policy level, politics and economics are linked. Governments can stimulate national economies, encourage new research projects, impose new taxes and introduce new strategies. A political choice by government can result in one of two approaches, a free market approach (Laissez faire) or centrally directed approach (Dirigiste approach).

In South Africa, in the pharmaceutical industry, there is a free market approach which is characterized by:

- Low entry barriers
- Encouragement of competition
- Little state support for industry
- Opportunities for wealth creation
- A belief in the laws of supply and demand
- High unemployment levels
- Production and quality standards being driven by profit motivation

The SA government does exercise direct control over the economy of the country. It is easier for drug companies to launch a growth or survival strategy when the national economy is showing steady growth with low inflation and when the international economy is not in a recessive pattern. Macroeconomic conditions in SA have started to shift towards a more positive climate, with a fall in interest rates and inflation and a favourable rand/dollar exchange. It is important as part of the strategic analysis process to consider macroeconomic forecasts as a predictive tool in their assessment. Key macroeconomic issues that are relevant to the pharmaceutical industry would be:

- Gross domestic product (GDP), total and per head of the population
- Growth in GDP

- Retain and consumer price indices
- Trade flows in imports, exports and the balance of payments
- Private sector share of GDP
- Foreign direct investment (FDI), total and as a percentage of total investment

In South Africa, the fluctuation of the rand/dollar and rand/pound exchange is also an important variable.

2.2.7 Analyzing government and industry relations

In addition to changes in macroeconomic conditions, drug companies have to be concerned with government changes in the economic environment specific to their industry. These include:

- Changes in government policy on the purchase of drugs: The State is the biggest customer base of drug companies in this country and a shift in policy to only supply generic substitutes of originator drugs at State hospital are reducing the profitability of the major pharmaceutical companies. Companies have to decide whether they move their focus to non-government sales in and outside this country or whether they engage government in a consultative process to compromise on the situation
- Cyclicality of demand: The State as an employer for the Public Service has a direct influence on the ceiling limits for medication benefits available. These limits on benefits usually for the lower to middle income consumer inadvertently create a cycle of demand, when benefits become exhausted, usually in the fourth quarter of every year.
- Industry negotiations on conditions of work: The SA government has introduced policy with regard to employment equity that directly impacts on the employment of expatriates in the drug companies, who are subsidiaries of MNC's.
- The fluctuating exchange rate has an implication for the cost of drugs in the SA market. Most MNC's in the pharmaceutical industry have a single exit price policy and when, there is an unfavourable exchange rate, products become unaffordable in this country and the marketing of these products becomes an impossible task, as cost is always raised by the service provider, as the limiting factor.

- Government's policy of actively supporting FDI's in this country is a positive one. However, there is a concern about pressure upon drug companies to open manufacturing plants in this country.

2.2.8 Analyzing the intensity of competition in an industry

Governments set the basic degree of competitiveness that they wish to see in industries. The degree of concentration of companies in a market is important as the total number of companies in an industry influence their ability to exert buying power over suppliers. The mix of companies making up the industry also impact on profitability. If there are a few companies that are roughly equal in size, there may be a tacit understanding between them to allow profits to grow. The concentration ratio is used to measure the degree to which turnover is concentrated in the hands of a few firms in an industry. In SA, in the antidepressant market, there are few major players with big marketing budgets that are able to drive the market. However, the market leader at present is Cipramil, a Lundbeck product that has achieved its position through consistent relationship marketing with its consumer base.

2.2.9 Competitive Rivalry

Competition usually results in a dynamic environment. Forces which affect competitive rivalry include the extent to which competitors are in balance.. There are several pharmaceutical giants in SA in the antidepressant market and there is a danger of intense competition as one competitor attempts to gain dominance. The growth stage of the market is also relevant. The antidepressant market in SA is still at the growth stage of the life cycle for the newer branded products but as the market matures and reaches saturation, this might change.

Further, the world pharmaceutical market is in a state of flux with mergers and acquisitions the order of the day. If the acquisition of weaker companies by stronger companies results in the provision of funds to improve the competitive standing of companies, their ability to compete in the hostile SA market effectively may be enhanced. There are low exit barriers for the major players in this market as they have an international presence. That is a factor of concern for the industry and for smaller companies who would not be able to withstand the assault from parallel imports.

Collaboration between the major players may be a more sensible route to achieving advantage especially in specific sectors, like CNS products. Such collaboration could begin with building barriers to entry to avoid substitution by generic drugs and parallel imports. Collaboration may also be advantageous for purposes of developing required infrastructure such as distribution channels, information systems or R & D activities.

Of relevance to this sector is that internationally because of the rapid scientific and technological change, high cost of R & D, high risk of failure and increasing buyer power, it is not uncommon for there to be collaboration through a variety of different alliances. Companies with brands in different markets like gastrointestinal and CNS would be able to collaborate to strengthen their individual brands. Lilly, a minor player in the gastrointestinal market could co-operate with launching a new product under another company with a strong presence's brand, to displace smaller competitors like Glaxo, in this market. The Human Genome Project is a classic example of how collaboration between companies and academia allowed more effective targeting of R & D efforts.

The major role players in CNS products differ in terms of:

- Product and service diversity
- Extent of geographical coverage
- Number of market segments served
- Distribution channels used
- Marketing effort – advertising spread and size of sales force
- Product and service quality
- Technological leadership
- R & D Capability
- Cost position
- Pricing policy
- Relationship to influence groups
- Size of organisation
- Extent of vertical integration

2.3 IDENTIFYING COMPETITIVE POSITION

One of the problems in analysing competition is that the boundaries of industries are not always clear. Strategic group analysis considers the extent to which companies differ in terms of various characteristics. One strategic tool available for this process is that of market segmentation.

2.3.1 Market Segmentation

A key advantage for any company is the ability to dominate a sector of the market and then target benefits that will sustain the position. The three stages of market segmentation are:

- The identification of the market segments
- The evaluation of segments
- Positioning within a market segment

Of relevance to the pharmaceutical industry, markets can be segmented according to the following strata in South Africa:

- Geographic: this has relevance specifically for rural versus urban areas
- Demographic: there are marked differences between the adolescent and geriatric market, in terms of value and affordability.
- Socio-economic and income: this is of relevance in the private sector especially for customer profiling.
- Ethnic group: there are significant differences amongst SA's ethnic groupings of attitudes to medicines and medical diagnoses.
- Benefits sought: There are segments of the population that are extremely health conscious who require safe drugs with minimal toxicity
- Usage rate and brand loyalty: Compliance and brand loyalty is probably a feature of the female and young adult market respectively
- Attitudes: there is a big difference between the genders with regard to attitudes to illness

For these factors to be taken seriously as segments, they have to be easily distinguishable, of sufficient size and reachable as a target market by drug companies. Certain segments would have more relevance than others for the marketing of products especially in situations where higher prices are paid for better quality.

An added advantage in a market that is so large is that a company's competitive advantage may be stronger in a segment than in the broader market. Closer matching of customer needs and the company's resources through targeting one segment can enhance sustainable competitive advantage. The reverse is also true. Concentration of marketing effort on smaller areas so that the company's resources are employed more effectively, may give smaller companies the edge.

In a market segmentation analysis, similarities and differences between groups of customers are identified (Johnson and Scholes, 1999:129). Relative market share is an important consideration and there is definitely a relationship between market power and performance. The pharmaceutical industry is a highly specialised sector, with established market leaders globally that have facilitated market entry into new developing markets and maintain a presence, even if market potential is a low percentage of the global market. These conglomerates have used their market power to secure the State health market in developing countries and have thus entrenched themselves in every new market. This is not just because of scale benefits of size but also because of 'experience curve' effects. The company that has built up most experience in the CNS market would have lower costs but also stronger relationships, hence having the edge in market share.

The following should be considered in the analysis of the industry's involvement in the public (State) and private sector:

- Buyer behaviour or purchase value e.g the investment government makes
- The attractiveness of each market segment in terms of return on yield, future growth prospects
- Relative market share in relation to competitors within market segments. This is of importance in the CNS products market as there is stiff competition amongst the leaders with little overall growth but changes in market share from month to month
- Market segments should suit competences therefore, pharmaceutical companies should consider their marketing budget allocation, if the State sector pursues its course with generic versus branded products

Porter and Ohmae (Lynch 2000), recommend that companies take the route of exploring where there are gaps in the segments of an industry. The starting point of any company wishing to sustain a competitive advantage is to map out the current segmentation position and then place companies and their products, in an industry into segments. It will become clear which segments are served or poorly served by current products. Table 2.4, illustrates this using three antidepressants.

Table 2.4: New or underutilized segment gaps

	Psych 1 **KZN**	**Psych 2** **Gauteng**	**Psych 3** **Western Cape**
Brand 1 (Prozac)			
Brand 2 (Zoloft)			
Brand 3 (Cipramil)			

Source: Internet 15

2.3.2 Perceived Value

The steps to analysing perceived value is as follows (Johnson and Scholes,1999:133):

- Identifying relevant market segments within which customers and competitors can be identified
- Defining the characteristic of the product or service most valued by the customers. This is usually done by market research.
- The third step is to rate how important these dimensions are to customers. Reputation and the need to provide good service and reliability are valued.

World leaders in this industry have traded on their reputation for creating shareholder wealth and have managed to stay off the recessive nature of the world economy. From 1992-1997, Lilly and Pfizer created enormous shareholder wealth: 40 % a year for Lilly by taking the transformational route and engaging the pharmacy management benefits program in-house, and Pfizer, 35% by taking the operational approach and building on its traditional strengths in research and sales. This was against an industry average of 28% (Internet 13).

2.3.3 Competitor Analysis

Pearce and Robinson (1997:86) stated that competitor analysis has three objectives: to identify current and potential competitors, to identify potential moves by competitors and to assist in devising competitive strategies.

According to Pearce and Robinson (1997:87) competitors are those firms that:

- have similar levels of commitment in the industry
- have similar definitions of the scope of their market
- provide similar benefits to customers and their products have a high level of substitutability

The pharmaceutical industry globally has a few major players that have entrenched themselves as market leaders that are highly competitive with each other. The smaller companies compete for the lesser share, at the same pace of competitiveness. The experience of the bigger companies sets the standard in that their respective skill sets have determined their chosen strategy and success over the years. Pfizer's style has been hard-driving and pragmatic, with aggressive investment in R & D, whereas Lilly built a strong management team and divested most of the non-core entities from its business portfolio.

Lilly's organisational team excelled at making timely portfolio decisions and tough strategic choices about first-mover investments to enter markets, investments in technology, make versus buy decisions and strategic alliances and relationships that fostered the development of a powerful drug portfolio. The functional structure was streamlined to five areas in which the company had a strong presence as well as unmet medical needs. The initiatives were driven from the top and this innovative vision to change jumpstarted their transformational strategy.

Pfizer focused its energies on its area of expertise. It exercised discipline in managing projects at every stage of development and used efficient management processes, including early input from marketing and a ruthless commitment to delivering practical results, to spearhead its initiatives.

2.4 ANALYSING THE COMPETITIVE ENVIRONMENT : FIVE FORCES ANALYSIS

A framework developed by Michael Porter known as Porter's five forces model can be used for industry analysis. It is an analytical model for assessing the nature of competition in an industry that is illustrated in Figure 2.10.

Figure 2.10: Porter's Five Forces Model

Source: Internet 15

This model is a means of identifying the forces which affect the level of competition in an industry. The analysis is most valuable when the influence on the immediate or more competitive environment is examined, rather than the more generalised level, where the value of the analysis is reduced.

2.4.1 Threat of New Entrants

Threat of entry to an industry largely depends on the extent to which there are barriers to entry. With the pharmaceutical industry, barriers to entry were historically high R & D costs, which required access to large amounts of capital. Other factors included clinical standards and regulations in different markets with increased development costs by duplicating the regulatory approval process. In recent yeas, governments have sought cost containment and drug companies have had to show that the benefits of new branded drugs are clinically desirable and quantifiable. The drugs have to perform better than existing drugs to ensure that they appear on 'approved medication' lists. Other barriers to entry can include:

- Economies of scale where in sales and marketing or production of goods and distribution, this factor assumes relevance
- Capital requirement of entry which varies according to technology and scale. The pharmaceutical sector is a capital-intensive industry.
- Cost advantages independent of size is related to early market entry and the established operators whose experience enables them to overcome market and operating problems. The increasing globalisation of markets and South Africa's change to democratic rule is facilitating market entry at present.
- Access to industry distribution channels, which may be a limiting factor as in most developing countries, infrastructure is poor leading to monopolies among logistic companies.
- Expected retaliation is a factor where there are established brand leaders. There are several world leaders in the pharmaceutical sector with a presence in South Africa and entry for smaller firms with restricted budgets may prove to be a costly exercise.
- Legislation or government action is of relevance to this sector. Legal restraints on competition are a reality in South Africa as there have been attacks on patent protection with parallel imports and regulation via legislation to control markets.
- Differentiation would be difficult for any entrant as there is resistance at MCC level to the development and launching of new branded products because of cost issues. Companies that have a reputation for reliability and quality, underpinned by product and quality specification at supplier level and strong

corporate values supportive of the quality image may be able to impact on the private sector.

2.4.2 The Power of Buyers and Suppliers

The forces of buyers and suppliers are linked and the relationship can have similar effects in constraining the strategic freedom in any industry. Buyer power is likely to be high when there is a concentration of buyers, especially if the volume purchases of the buyers are high. The public sector in SA at the moment uses this to leverage for cost reductions in pharmaceuticals supplied to the State hospitals. This has a detrimental effect on the private sector development if branded products are available for less in the public sector. This power is further increased when there are alternative sources of supply as is the case with parallel imports. This is even where there is product differentiation because of deregulation spawning a host of entrants into the generic market.

The high cost of branded medication due to the single exit price policy of major pharmaceuticals means that the cost of switching to generic medication is low and involves little risk. There is the constant threat of backward integration by government if satisfactory prices or quality from the drug companies cannot be obtained.

There are factors that can boost supplier power in this industry. The pharmaceutical companies need to ensure that there is a concentration of suppliers rather than a fragmented source of supply, therefore joint ventures with regard to government is a possibility to be considered. There may be hidden costs to 'switching' which may become more obvious with time as effectiveness of parallel imports and generic medication still has to be established. Companies have to become innovative and develop unique, strong brands that are effective such that switching is not an option. There is always the possibility of the supplier integrating forwards if it does not obtain the prices and hence the margins, it seeks. As the socioeconomic status of South Africans improves, there is the possibility that the bargaining power of the consumer would be reduced with fragmentation of the consumer base.

2.4.3 Threat of Substitutes

Substitute products lower industry attractiveness and profitability as they limit price levels. At present, with the focus on generic medication, there is product-for-product substitution that has been enforced by legislation. This places a ceiling on prices for the industry and makes inroads into the market, reducing its attractiveness. This represents a serious threat to branded products which need to be thwarted by focusing on representation to the consumer of the higher benefit or value of branded products. Companies need to strengthen the perceptions of the consumer that branded is better. Costs remain an issue and companies need to examine the extent to which the risk of substitution can be reduced by building in switching costs through added product or service benefits meeting consumer needs.

2.5 ANALYZING CORE COMPETENCES AND STRATEGIC CAPABILITY

Core competences are those capabilities that are critical to the achievement of competitive advantage (Johnson and Scholes, 1999:160). Competition between businesses is a race for market position and market power as well as competence mastery.

2.5.1 Assessing competences

Table 2.5 illustrates the changes in functional capabilities that are associated with each of the four basic phases in an industry lifecycle. Shakeout is the phase between growth and maturity and requires a mixture of functional capabilities.

Table 2.5: Functional capabilities in an industry lifecycle

Functional Area	Introduction	Growth	Maturity	Decline
Marketing	Resource and skill to create awareness and find acceptance from customers	Ability to establish brand recognition, find niche, reduce price, strong distribution relations and develop new channels	Skills in aggressively promoting products to new markets and holding existing markets; pricing flexibility; skills in differentiating products and holding customer loyalty	Cost effective means of efficient access to selected channels and markets; strong customer loyalty or dependence; strong company image

Production/Operations	Ability to expand capacity, limit the number of designs and develop standards	Ability to add product variants; centralize production or lower costs; ability to improve product quality	Ability to improve product and reduce costs; ability to share or reduce capacity; advantageous supplier relationships	Ability to prune product line; cost advantage in production; location or distribution
Finance	Resources to support higher net cash overflow and initial losses; ability to use leverage effectively	Ability to finance rapid expansion; to have net cash outflows but increasing profits; resources to support product development	Ability to generate and redistribute increasing net cash inflows; effective cost control systems	Ability to reuse or liquidate unneeded equipment; advantage in cost of facilities; streamlined management control
Personnel	Flexibility in staffing and training new management; existence of staff with key skills in new products or markets.	Ability to add skilled personnel; motivated and loyal work force	Ability to cost effectively; reduce work force and increase efficiency	Capacity to reduce and reallocate workforce; cost advantage
Engineering	Ability to make engineering changes, have technical bugs in product and process resolved	Skill in quality and new feature development; ability to start developing successor products	Ability to reduce costs, develop variants and differentiate products	Ability to support other grown areas or to apply product to unique customer needs
Key functional area and strategy focus	Engineering and market penetration	Sales; consumer loyalty and market share	Production efficiency and successor products	Finance; maximum investment recovery.

Source: Pearce and Robinson, 1997

The goal for senior management is to focus attention on competences that really affect competitive advantage. Most service industries are currently experiencing the need to innovate in relation to innovative ways of redesigning services and their delivery from 'direct-line selling' to exploitation of the Internet.

Companies develop key areas of expertise which are distinctive to that company and critical to the company's long- term growth over time (Prahalad and Hamel:1990) However, core competences change over time. Companies have a responsibility to develop areas of expertise in the critical, central areas of the company where the most value is added to its products and should change in response to changes in the company's environment and evolve over time.

Three factors assist in the identification of core competences in any business and include that which:

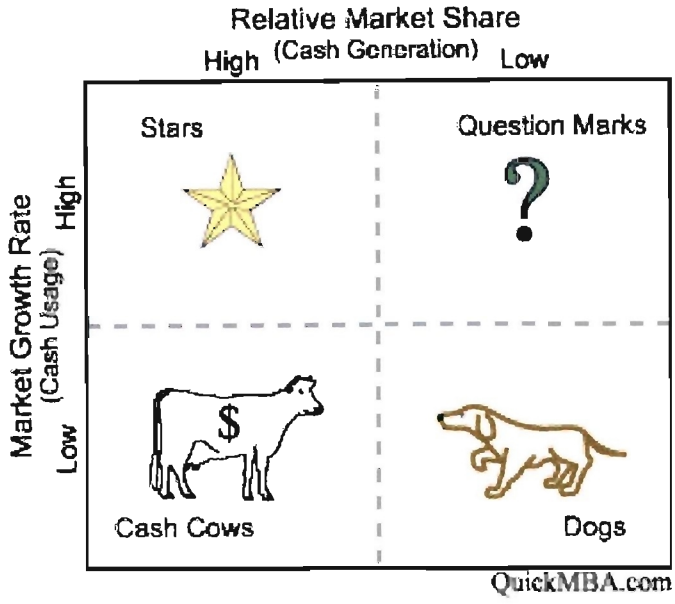
- Provides potential access to a wide variety of markets
- Makes a significant contribution to the perceived customer benefits of the end product
- Is difficult for competitors to imitate

The management of the linkages between a primary and support activity forms the basis for core competence and drug companies need to make key investments in systems or infrastructure or in the processes of innovation which provide the basis on which the company outperforms competition. The ability to coordinate the activities of specialist teams creates advantage by improving value for money in service delivery. Investment in manufacturing in Africa would be a huge competitive advantage for a major player as FDI is a vital key to government.

2.5.2 The BCG Growth Share Matrix

The BCG Growth Share Matrix is a portfolio approach to strategic analysis based on two key variables: market share and market growth. The entities within the portfolio e.g. market segments can be positioned within the matrix, and strategies developed based on their relative position. The four quadrants of the matrix, derived by categorising the two variables into "high" and "low", allow businesses to be categorised. Figure 2.11 shows the various quadrants of the matrix.

Figure 2.11 : BCG Matrix



Source: Internet 11

In the case of the pharmaceutical companies operating in SA, this matrix could be used to assess the different CNS products in the product portfolio into:

- Stars which represent the best long-term prospects in a portfolio that should be nurtured and invested in for long-term benefit.
- Question Marks are those products that could be turned into stars if invested in or divested of if need be.
- Cash Cows represent those products that are yielding high returns in a stable environment that can be 'milked'.

Dogs represent those products/businesses which have to be divested, that are draining the resources of a company.

2.5.3 Identification of key issues

An analysis of Strengths, Weaknesses, Opportunities and Threats (SWOT) can give an indication of strategic capability. This can also be done by assessing the extent to which resources and competences relate to critical success factors (Johnson and Scholes, 1999:193).

2.5.3.1 SWOT Analysis

Internal analysis identifies strengths and weaknesses and external analysis reveals opportunities and threats. The SWOT analysis is an important tool for auditing the

overall strategic position of a company and its environment and can be used in conjunction with other tools for audit and analysis. Each of the companies involved in this sector needs to re-visit their product portfolio, re-assess their human capital and its' goodness of fit to the South African market, develop innovative ideas to deal with the legislative changes and consider benchmarking and competitor profiling to assist them with developing a sustainable competitive advantage. Developing a relationship with providers of service is now going to be challenging without the benefit of marketing activities that the industry was accustomed to. Warding off the threat of generic substitution is probably the biggest threat facing the industry since the new legislation and companies with branded products have to find a way to increase market share for their products. Consumer advocacy remains an untapped area of resources available to the companies and that needs to be harnessed. The industry has been fairly closed to a few players whose strengths are their established market leader positions internationally, their reputation for innovation and their market power. These strengths need to be built on to include building relationships with government in private-public sector partnerships that will ensure that the existing market for branded products remains in this country.

The public sector could also be analysed using a SWOT analysis especially in the light of government's desire to streamline the low to middle income groups' health care via public-private sector partnerships. Appendix Three is a brief analysis of the strengths and weaknesses of services at a State facility.

2.5.3.2 Critical Success Factors

Critical success factors are those components of strategy in which an organisation must excel to gain competitive advantage (Johnson and Scholes, 1999:192). The major players are experienced at this in the international arena. Smaller companies can use benchmarking to develop their own edge in the market.

2.6 INTERNAL ANALYSIS

Johnson and Scholes (1999:149) stated that successful strategies are dependent on strategic capability to perform at the level required for success that is linked to three main factors. These include the resources available to the organisation, competence with which activities are undertaken and the balance of resources and activities. The

resources and competencies must fit the environment in which the organisation operates and the opportunities and threats, which exist.

2.6.1 Resource Audit

The resource audit identifies the resources available both within and outside an organisation to support its strategies. The quality, nature and extent of resources to support the strategies should be assessed. (Johnson and Scholes, 1999:153). In view of the changing rules of the market, most companies have embarked on a process of rationalisation of business practices, resource allocation and human capital investment. A significant factor in the South African industry, would be to ensure that the company is compliant with the employment equity requirements of government.

2.6.2 Value Chain Analysis

The value chain is a systematic way of examining all activities an organization performs and analyzing the interaction to determine sources of competitive advantage. The value chain is all of the information and physical activities that flow within and between an industry and its suppliers, distributors and customers. The industry's value chain is also described as a system of interdependent activities, which are linked together. Vertical integration is the way forward as co-operative measures are undertaken by stakeholders on the same side of the equation. Co-payments from consumers is one way forward for the branded product market in SA.

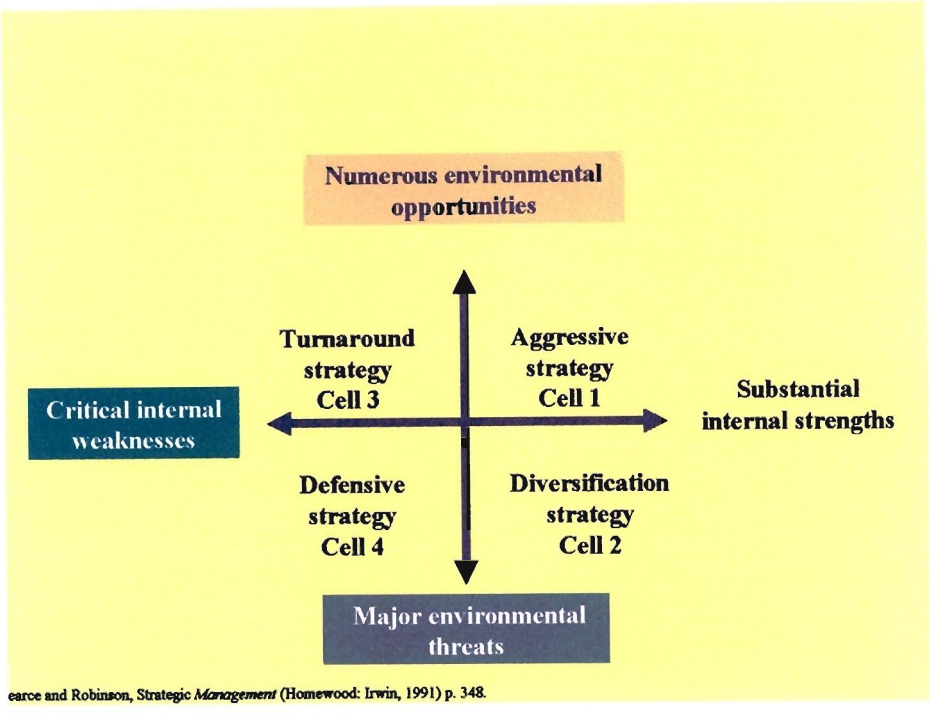
2.7 STRATEGIC CHOICE

Strategic options have to be compared both logically and politically and aligned, acceptable, and feasible in the process of a strategic choice for the way forward in this country. The legislative changes are here to stay and government's pressure to reduce the costs of branded products is unlikely to abate, hence companies have to develop strategies that are flexible and adaptable to the new South African business climate.

2.7.1 The SWOT Matrix

In the SWOT Matrix key external opportunities and threats are systematically compared with internal strengths and weaknesses (Pearce and Robinson, 1997:170). Figure 2.12 is a diagrammatic representation of a SWOT matrix.

Figure 2. 12: SWOT Matrix Diagram



Source: Internet 12

Cell I is the most favourable situation as there are many environmental opportunities and strengths that encourage the pursuit of the opportunities. This situation favours growth oriented strategies. Companies that wish to increase their market share need to aggressively discover innovative ways to not only retain their customer base but also actively make inroads into new markets to counteract the negative impact of the growth in the generic and alternative medicine market.

Cell 2 illustrates a situation where there are major environmental threats and substantial internal strengths. Strategies should encourage the use of current strengths to build long-term opportunities in a more favourable environment. The major threat comes from parallel imports and companies need to constantly engage government in a process of mutual co-operation to shift this policy.

Cell 3 displays numerous market opportunities but firms are constrained by their internal weaknesses. This needs to be eliminated before they can effectively pursue

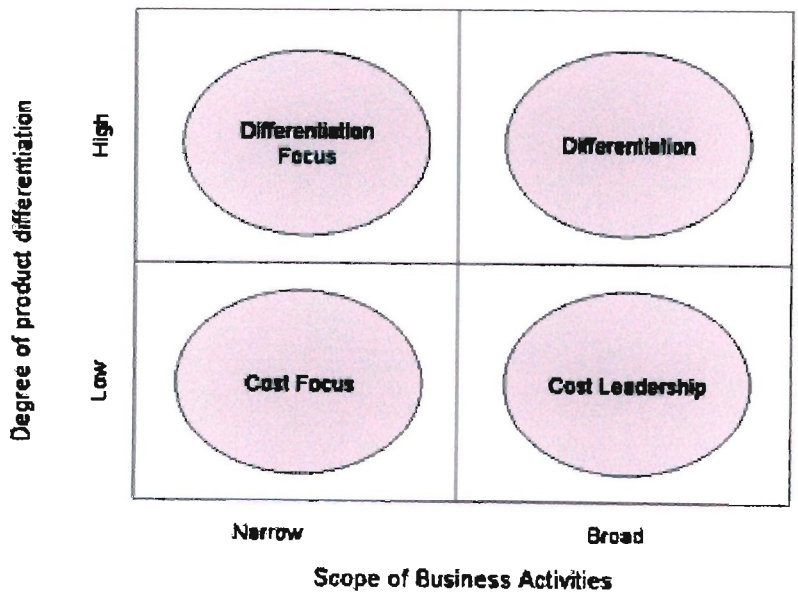
market opportunities. Smaller companies that are stifled by structural problems and limited budgets, need to rationalise services, develop a niche for their products and focus on service delivery as a core competence.

Cell 4 is the least favourable situation as there are major environmental threats and critical internal weaknesses. Strategies that reduce or redirect involvement in the products or markets examined by the SWOT analysis should be encouraged (Pearce and Robinson, 1997:172). At present , a case can be made that SA is a hostile market, however, this is a pessimistic view of the situation.

2.7.2 Generic Strategies

Michael Porter suggested four "generic" business strategies that relate to the extent to which the scope of a business's activities could be differentiated in order to gain competitive advantage. The four strategies are summarised in Figure 2.13 below:

Figure 2.13: Generic Strategy Matrix



Source: Internet 12

The differentiation and cost leadership strategies seek competitive advantage in a broad range of market or industry segments. The differentiation focus and cost focus strategies can be adopted in a narrow market or industry. At present, the market in South Africa is narrow for branded products and product differentiation and cost

reduction is the only way that companies would be able to sustain competitive advantage.

2.7.3 Grand Strategies

Basic directions for strategic actions are provided by the grand strategies which are the basis of efforts directed at achieving long-term business objectives (Pearce and Robinson, 1997:218). Fourteen principal grand strategies include: concentrated growth, market development, product development, innovation, horizontal integration, vertical integration, concentric diversification, conglomerate diversification, turnaround, divestiture, liquidation, joint ventures, strategic alliances and consortia. The principle purpose of the grand strategy to overcome weaknesses or maximise strengths is compared to the choice of an internal or external emphasis for growth and profitability (Pearce and Robinson, 1997:265).

2.7.3.1 Market development

Figure 2.14 Ansoff's Product/Market Matrix

Product / Market	Present	New
Present	Market Penetration	Product Development
New	Market Development	Diversification

Source: Internet 15

Ansoff's model in Figure 2.14 describes four different ways that companies can relate to markets via market penetration and development, product development and diversification. Three ways of developing a market involves: extension into other market segments which are not currently served; developing new uses for existing products and geographic expansion (Johnson and Scholes, 1997:292). All of these are

feasible options for the major role players who have the internal capacity to develop the market within the SADC region and Africa. The world market leaders have an opportunity to increase the market for their range of products in SA, which is still regarded as a developing market.

2.7.3.2 Product Development

Product development involves the marketing of new and modified products to existing customers via the existing distribution channels, developing new product features, quality variations and additional models and sizes (Pearce and Robinson, 1997:225). The success of this strategy would depend on the ability to analyse and understand the changing needs of customers. Strategic development should be built around such a core competence. The major players already have this as their core competence internationally. What would be vital is the location of a manufacturing plant in this continent. Government is suspicious of the R & D plans of the major companies as patient subjects are easy targets for clinical trials but an actual plant, would address this by indicating a commitment to stimulate the local economy.

2.7.3.3 Concentric Diversification

Concentric diversification involves the acquisition of businesses that are related to the acquiring firm in terms of markets, products or technologies. In the ideal scenario profit potential is high, exposure to risk is reduced and resource demands are minimal (Pearce and Robinson, 1997:229). There have been widespread changes internationally and in South Africa where there have been mergers of smaller companies with the major players, divesture of generic divisions and acquisitions of generic companies.

2.7.3.4 Conglomerate Diversification

Conglomerate diversification refers to a situation when a large business acquires a business where the sole reason for the acquisition is profit considerations (Pearce and Robinson, 1997:230). Pfizer Laboratories has embarked on this in the last two years to become the largest pharmaceutical company in the world.

2.7.3.5 Horizontal Integration

Horizontal integration is a form of related diversification. The intention is to eliminate competitors and to gain access to new markets (Pearce and Robinson, 1997:227). Collaboration between stakeholders in the SA market is the way forward.

2.7.3.6 Vertical Integration

Vertical integration is a form of related diversification. It involves the development into activities, which are concerned with inputs into current business to allow organisations to grow their market share, improve economies of scale and increase efficiency of capital use (Johnson and Scholes, 1997:294). This has already been commented on and it is a viable option for suppliers of service and the industry.

2.7.3.7 Strategic Alliances

In a strategic alliance the companies do not take an equity position in one another (Pearce and Robinson, 1997:237). An example of a strategic alliance includes:

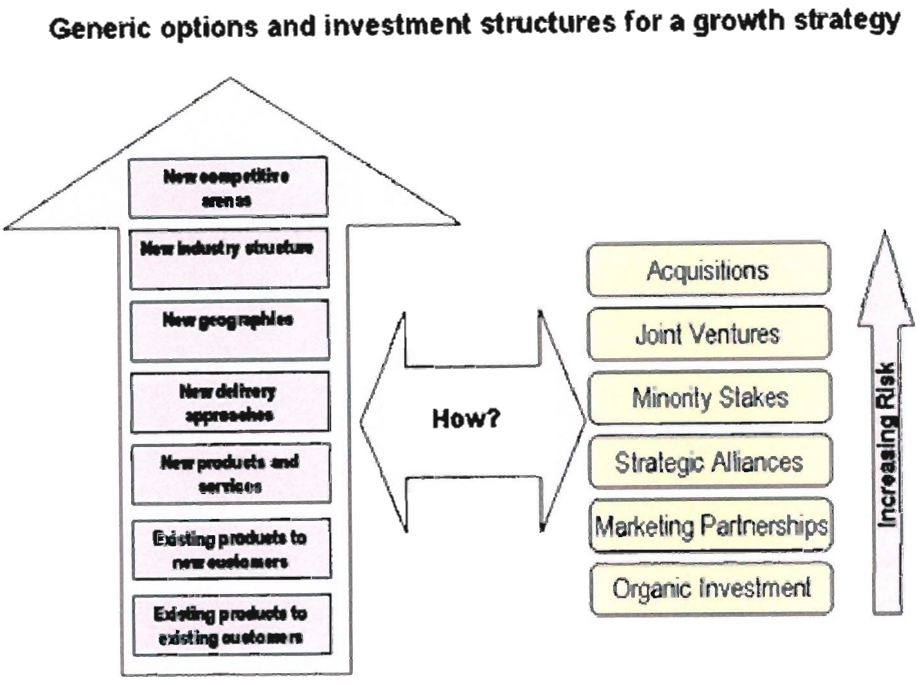
- Licensing which involves the transfer of property rights. Patents or trademarks is granted to licensee for a specified time in return for a royalty and for avoiding tariffs or import quotas. This is one option open to companies that do not want to lose their intellectual property rights.

Companies like Pfizer SA and Lilly SA have competitive advantage that can be traced to one of these three roots: superior resources, superior skills or superior position. As a result, the companies have a positional advantage in the global market over companies like Lundbeck. Once attained, a good position is defensible. The companies return enough value to warrant continued maintenance and would be so costly to capture that rivals are deterred from full-scale attacks on the core of the business. This positional advantage is associated not just with size or scale but with the ownership of strong product pipelines and having a global geographical presence. Smaller R & D companies like EISAI enter into strategic alliances with the R & D division Pfizer for the purpose of developing their molecules. The reality is that it costs a fortune to bring a drug to market and these companies only way forward is to engage these market leaders in strategic alliances. For Pfizer, it represents the possibility of adding a new molecule to its database of possibilities.

2.7.4 McKinsey Model

The McKinsey model looks at how businesses should develop their growth strategies as summarised in the Figure 2.15 below:

Figure 2.15: The McKinsey Model



Source : Internet 12

Growth in individual companies can be achieved by looking at business opportunities along several dimensions based on:

- Operational skills
- Privileged assets
- Growth skills
- Special relationships

In the SA pharmaceutical industry, growth will only be achieved, if the market leaders actually invested in local manufacturing companies. The growth in the industry remains below the industry average internationally as there are more companies, taking a piece of the pie and very companies that are taking responsibility to create 'more pie'.

2.8 STRATEGIC EVALUATION

Strategies can be assessed against three evaluation criteria: suitability, acceptability and feasibility.

2.8.1 Suitability

Johnson and Scholes (1999:319) describe suitability as a broad assessment of whether a strategy addresses the circumstances in which an organisation is operating. This involves establishing the rationale for each strategic option and establishing the relative merits of each one.

Establishing the rationale consists of assessing the extent to which a strategy:

- exploits the opportunities in the environment and avoids threats
- capitalizes on the organisations strengths and core competencies and avoids or remedies the weaknesses
- addresses the cultural and political context (Johnson and Scholes, 1999:322)

Tools used to test for suitability include: lifecycle analysis, value chain analysis, portfolio analysis, positioning and business profile (Johnson and Scholes, 1999:321). It would be very important for drug companies to assess the portfolio of their SA subsidiaries to assess whether they are strategically positioned in this market. The political context is changing, but this is a universal phenomenon and so drug companies need to revisit their business portfolio and tailor it to the changing world market. In the developed world, like Europe and the UK, the market us fairly mature but in the developing countries, the lifecycle stage is still at a growth phase.

2.8.2 Acceptability

The acceptability of a strategy is concerned with expected performance outcomes and the extent to which they fit the expectations of stakeholders (Johnson and Scholes,1999:319). This is assessed according to three issues: the expected return from a strategy, the level of risk and the likely reaction of stakeholders. Drug companies face increasing pressure from their shareholder base to meet performance goals and in SA, government is facing an election soon in which its ability to translate policy into action will be critically assessed.

2.8.3 Feasibility

Feasibility is concerned with whether an organisation has the resources and competencies to deliver a strategy (Johnson and Scholes, 1999:319). Fund flow analysis, break-even analysis and resource deployment analysis can be used to assess feasibility (Johnson and Scholes, 1999:350). Most of the players in the SA market are global leaders who are profit-driven. The attack on patent rights may seriously impact on the companies' bottom-line and is a situation that has to be addressed. The companies should also assess the feasibility of entering the African generic market, specifically with a manufacturing facility.

Markides (2000) stresses that the process of developing superior strategies is part planning and part trial and error. He argues that analysis and planning will not produce a fully-fledged strategy ready for implementation but will help narrow the options. Hamel (2000) claimed that the current environment is hostile to industry incumbents and hospitable to industry revolutionaries who radically reconceive products and services, not just develop them, redefine industry boundaries and redefine market space.

2.9 STRATEGIC CHANGE

Gemini's framework for planned strategic change is a useful starting point to consider this aspect of strategy. Business transformation is seen as a four-dimensional process of re-framing, i.e. questioning what the organisation is and what it can achieve so as to open up new possibilities and challenges. Companies need to achieve mobilisation before creating a vision and building a measurement system to assess response to change. Restructuring deals with a company's structure and is usually associated with cultural change. A company would have to construct an economic model before aligning the physical infrastructure to ensure strategic fit. A redesign of the work architecture or processes would ensure that the process added value. Revitalising is about achieving a goodness of fit with the environment by achieving market focus first and then inventing new business. Companies would have to change the rules of competition to provide new bases for it through product or process differentiation.

Finally, renewal creates a reward structure to ensure a culture of acceptance of change and encourages individual learning to develop the organisation (Lynch, 2000).

2.9.1 Enforced Choice

There are some circumstances where the strategic development of an organisation is largely imposed from outside. This may be because major changes in the environment overshadow other considerations. In this scenario, the organisation may be seen as a 'victim of circumstance'. The danger of enforced choice is that the risk profile of a company increases. Scenario planning becomes a vital tool in developing contingency plans. The regulatory changes that have been imposed onto this sector by government represent exactly this scenario. The reality is that change is here to stay and companies need to adapt to manage the change process. In fact the environmental rule change by government may have acted as an unfreezing mechanism in an industry that was ready for change. Managing the unfreezing process is not easy as the whole situation is in a state of flux. Diagnosing strategic change needs, information building and strategy workshops to facilitate a change in tactics, to communicate change, change routines and define roles in the change process, are important steps in the process of accepting change (Lynch, 2000).

2.9.2 Expansion strategies

Innovation cannot be institutionalized so strategic planning is not a replacement for intuition and creative thinking. In the current world climate, companies have to do more than just develop new products and enter new markets to maintain their competitive edge. Companies have to consistently come up with ideas that differentiate them from others for there to be growth.

2.9.2.1The Market Options Matrix

This model is a useful way to start considering strategic options for expansion in a climate of change as it presents the product and market choices open to a company. It considers the possibility of launching new products and moving into new markets and explores the possibility of withdrawing from markets and moving into unrelated markets.

Withdrawal is considered when the product life cycle is in the decline phase with the possibility of retrenchment a valid option. Over-extension of product range is occurring worldwide and holding companies are selling their subsidiaries, as funds are needed for investment elsewhere. De-mergers are also not unusual but it is usually a strategy used to realize the underlying asset value in publicly quoted companies. Privatization in SA is a positive way to realize real value as state-owned assets have inherent value. Government is looking for private-public sector partnerships and for models from industry with regard to an NHS system.

Market penetrating strategy should begin with existing customers. Existing companies with low relative market share in a growing market can attack aggressively the market or a segment. Companies with smaller market share need to take charge of this process. Where there is a high relative market share, there is risk of loss so predatory price cutting sometimes keeps out smaller new entrants. GlaxoSmithKlein has consistently taken this view in SA and kept Aropax as the lowest price of the ethical antidepressants in the serotonin class of drugs.

Market development strategy has allowed companies to move beyond immediate customer focus and attract new customers from existing product range by seeking new segments, new geographical areas or new uses for products. A classic example is Aropax which has now been registered in SA for about five more indications than when it was first launched. Product development for the existing market is really in the territory of the big R & D players who use this to counter competitive entry, maintain the lead as product innovators, thereby protecting overall market share.

Diversification into related markets in the SADC region and Africa is a real possibility and can include: Forward integration in the company's outputs via distribution, transport and logistics, or backward integration by extending activities to the provision of inputs like raw materials. Acquisitions have been popular in this country and it is probably because this method of market expansion is associated with gaining assets of a company: its brands, market share, core competencies and technology. This route is also chosen for competitive reasons.

2.9.3 Strategic change in government agencies

Profitability and shareholder value are the drivers behind private sector planning. Government agencies struggle with defining and measuring the 'bottom line'. Even a focus on service delivery to 'customers', is not really helpful in this situation. Strategy in public organizations is governed by broader public policy issues like politics, where the political policy of government guides strategic development and monopoly supply as public authorities often have the monopoly as suppliers of a service. Part of the problem is that they are under pressure to operate efficiently but are unable to spend any surplus profits they generate. They are also subject to changes in government policy direction and lack the consistency of private organizations. The lack of choice for consumers at these agencies means that suppliers of service are not really subject to the market pressures that affect business strategy in the private sector. (Lynch 2000:31). Faced with pressure for change from politicians who need to see health care service delivery improve, managers often resign and enter the private sector.

Subsidiaries of MNC's are not very far off from the same level of frustration as leaders in the public sector. They are subject to restrictions with funds, headcount, and limiting factors at a policy level. The parent company shows them the field to play on but do not allow them to take the initiative in the local market. In the public sector it is similar as whatever the government says, has a massive effect on where policy goes as there is always an overlay of the party political position.

2.10 STRATEGIC OPPORTUNITIES FOR PROVIDERS OF SERVICE

With the changes in legislation, especially the licensing of dispensing doctors, the removal of incentives and sampling and the flooding of the market with generic medication, healthcare providers have embarked on ambitious, cost-reduction initiatives in an attempt to improve their financial position. Some have mounted significant attempts to optimize payment for healthcare services, revised coding procedures, implemented more thorough charge-capture mechanisms, reviewed terms of their managed care contracts and ensured payer compliance with contract terms.

Strategic planning will uncover new revenue-generating opportunities for health care providers including:

- Increasing market share by expanding the breadth and depth of service delivery
- Filling gaps in the continuum of services by partnering with other providers or developing new services not currently provided for in the area e.g. 3D ultrasound at obstetric practices
- Developing niche services that are not sufficiently available in the area
- Re-packaging existing services to address specific market segments

2.11CUSTOMER-DRIVEN STRATEGY

Customer-driven strategy is concerned with meeting the needs of the company's actual and potential customers, and as a result, delivering the objectives of the company. The customer-driven concept argues that only by attracting and retaining customers will long-term profits be maintained (Lynch 2000:201). SA companies have begin to realize that simple financial measures of profitability are not enough to ensure the growth and survival of a company. There has to be a link with customer satisfaction and loyalty. Lynch (2000) stated that there is empirical evidence to suggest that loyal customers are more profitable as they tend to account for the majority of sales and their loyalty means they are less sensitive to price increases and may even encourage new customers, attracting new customers costs organizations more than retaining loyal customers and retaining existing customers can drastically increase profits.

There are three main strands to this strategic approach:

- Understanding the customer: By directing customer contact at many levels, widely disseminated research on key customer findings e.g. on segmentation, knowledge of why customers choose the company's products
- Responsiveness of the company to customer needs: The company regularly receives and acts upon customer satisfaction surveys versus competitors, is responsive to customer complaints and suggestion and tracks key customer data on company image versus its competitors
- Provision of real value for money: The company needs to monitor quality relevant to the positioning of products in the market place, conduct

comparative surveys of competitors' prices and service offerings and rewards inside the company based on performance with customers.

Five possible elements of customer added value include:

- Differentiating capabilities: a unique location of service outlet will tie customers to the company, product differentiation in a niche market
- Channel power: Develop real dominance in the delivery of service to the customer
- Company reputation: The knowledge and trust of years of trading in the market bonds customers to a company
- Brands: The names of the products or services that distinguish the company from others
- Customer relationships: formal and informal relationships that link customers with their suppliers

2.11.1 Customer profiling

Customer profiling is clearly related to the sustainable competitive advantage of the company as it helps to identify why some customers choose one product over another. Customer profiles describe the main characteristics of the customers and how they make their purchase decisions. Customers can be profiled according to:

- Domestic customers who buy products and services for themselves or their families. This is called primary demand that is influenced by the industry itself. The product must work however and give customer satisfaction. This group of customer can be persuaded to purchase products by pricing, branded goods and advertising and by quality and service levels; these elements form the basis of the sustainable competitive advantage between companies.
- Large business customers tend to buy for more rational and economic reasons. Demand is often derived demand: influenced by factors in another industry
- Not-for-profit charity consumers will involve service, focused benefits, and value for money

There are three areas where customer profiling supports competitive advantage:

- Customer switching costs: This is the cost to the customer of changing its purchase from the company and moving to another supplier. If costs are high, then switching may not occur
- Customer bargaining power
- Customer cooperation

2.11.2 Branding

Branding is a specific name or symbol used to distinguish a seller's product or service. It allows a product to be at a higher price than a functionally equivalent non-branded version. Reputation is a broader concept, which refers to the sum of customer knowledge developed about a company over time and is based on:

- Product performance: customers experience forms their basis for their judgement about a product
- Quality: customers expect certain levels based on pricing, positioning, advertising and built-in performance levels
- Service: customers may be offered differing levels of delivery, advice or other forms of customer experience
- Marketing support: advertising, packaging and promotional activity

Five areas have to be analyzed when considering this aspect of strategic analysis:

- Does the product have a reputation?
- Does it have continuity?
- Does it have a distinctive formula that is difficult for others to replicate?
- Does it communicate the company's position as an established player in the market?

2.11.3 Communicating with customers

Companies communicate with their customers in order to:

- Inform them about their products
- Persuade them to purchase or continue buying their products or services
- Establish and secure the competitive advantages of their products

In most situations, personal persuasion is the most cost effective method of communication because the message can be tailored to the individual customer. Mass marketing is required and would involve: advertising, branding and promotion. The key criterion is cost effectiveness which is measured by the cost of obtaining an effective communication with the customer which is measured by the sale of the product.

Communications can include:

- Branding: powerful way to retain customer loyalty in mass market products
- Personal selling: personal relationship and individually tailored message for a single customer to purchase the product
- Technical promotions: the use of technical presentation of data on the product
- Consumer promotions: devices that promote the product without building any relationship. Effective where customer loyalty is low or a new product is being introduced
- Public relations and sponsorship: lobbying of government and other stakeholders

Communications directed at customers will be seen by other stakeholders like employees, shareholders, government, trade unions, suppliers and consumer groups.

2.11.4 Strategic pricing and value for money

In the longer term, pricing strategy can be a major factor in competitive advantage because it significantly alters the basis on which companies can compete. Pricing is important because of the impact of prices on profitability, positioning of the product in the marketplace and value-for-money impression created. Price changes have more than twice the impact on earnings compared with volume changes (Lynch 2000: 224).

The pricing decision is a balance between two factors:

- Costs: setting the price above the marginal cost of production
- Competition: pitching the market price significantly above competition even if product differentiation doesn't help sales

The strategic role of price is involved in price discounting .For some customers quality, availability of stock, product performance, after sales service and brand value are as important.

Government purchases are made on the basis of competitive price comparisons. Products that perform to acceptable industry standards and are available are negotiate with over: the size of the order, the importance of the customer in terms of annual sales, the costs of production and the prices and terms offered by competitors. Traditional practice is that of cost plus pricing where the costs are added up, a percentage profit is applied and the final price is determined. Target pricing occurs where the price is set primarily on the basis of the competitive position of the company rather than the costs. So, the overall process in pricing decisions of companies should include: evaluation of competitor's pricing, establishment of price objectives and consideration of competitors and the product life cycle and set prices.

2.12 CONCLUSION

This chapter discussed the strategic theory and strategic analysis that can be used to evaluate stakeholders, mainly pharmaceutical companies. The next chapter will discuss the South African pharmaceutical industry in greater detail, evaluating the role each stakeholder plays in it. It is important to for all stakeholders to recognise that the legislative changes are here to stay. The choices open to the pharmaceutical industry are to:

- Do nothing, that is continue with present strategies
- Withdraw by leaving the market
- Consolidate by attempting to hold market share in the existing market.

It is important that drug companies, even if they are market leaders:

- Have senior leadership who "own" their strategic planning processes
- Employ a consistent, well-understood and structured planning process across all levels of the company
- Use effective internal communication to link planning to practice

- See planning as a continuous process and view the process as more important than the product
- Tie performance measurement to incentives that require accountability for results
- Understand that customer-driven strategic planning has to be linked to culture change for it to be successful (Lynch:2000).

CHAPTER THREE: THE SOUTH AFRICAN PHARMACEUTICAL INDUSTRY AND THE LEGISLATIVE CHANGES

3.1 INTRODUCTION

The stakeholders in the South African pharmaceutical industry, specifically in the market for CNS products, include international giants like Pfizer Laboratories, Eli-Lilly, GlaskoSmithklein and Jansen-Cilag, whose investment in South Africa represents approximately 1% of their US market and less than a percent of their global turnover. The South African subsidiaries are locally registered as companies, however, their strategic direction is decided by senior management in the parent company, usually in the United States. South Africans are employed at regional and national level in positions including those of marketing representatives and sales and product managers, however, the chief executive officers are usually expatriates, who serve terms of office ranging from between two to five years in this country. There is however, a commitment to the development of the market in South Africa as it is seen as a springboard into Africa and most companies are co-operative with the goals of the South African Government in making health care affordable for most South Africans.

3.1.1 Historical Background

The relationship between the SA government and pharmaceutical companies came under the spotlight of international attention in the last five years over the issue of availability of products to the majority of the population at affordable prices. It reached a head to head confrontation over the issue of anti-retroviral drugs and the parallel importation of generic substitutes from other countries into South Africa, which undermined the branded market. The issue was resolved when the companies withdrew their class action suit against government, regarding patent rights and attempts were then made to facilitate a process whereby a consultative process would result in legislative changes that would benefit all stakeholders.

The pharmaceutical industry was initially consulted during the development of the National Drug Policy and in January 1998 proposals were made to the industry to deal with some of their concerns about developing regulations under the Act. However,

because of the seriousness of the issues at stake and the implications for the international pharmaceutical industry, litigation was the preferred choice by the industry. Provisions of the Medicines Act that related to intellectual property rights were at the heart of the court case.

The pharmaceutical companies first brought this action in 1998. At that time, they obtained an interim interdict which prevented the Government from implementing the contested sections of the Medicines Act, pending the outcome of the forthcoming case. At virtually the same time, the United States Trade Representative put South Africa on the Special 301 Watch list in May 1998, acting in terms of the United States Trade Act of 1974. Eighteen months later it dropped South Africa off the 301 Watch List. This followed talks between the two governments that led the White House to release a statement declaring that "the two governments have identified common ground with respect to South Africa's implementation of its so-called 'Medicines Act'" (Internet 5). The United States had accepted the South African government's assurance that it would honour its international commitments that fully protected intellectual property rights. The basis for this belief was that the provisions of the Act were not inconsistent with the Trade Related Intellectual Property Rights (TRIPS) Agreement.

3.1.2 The Issues Involved

The drug companies had contended that numerous sections of the Medicines Act contradicted the Constitution of South Africa. These included:

- The extent of the powers conferred on the Minister of Health.
- Deprivation of intellectual property in a manner that amount to expropriation without compensation
- Various forms of discrimination against sections of pharmaceutical industry
- Restriction of freedom of trade
- Failure to comply with legislative procedures set down in the Constitution (Internet 6).

The South African Government's drug policy was driven mainly by domestic factors, but the international dimension was also relevant and the dispute became part of the

larger international debate on access to affordable health care for developing countries and for the poor in wealthier nations. The SA government saw the withdrawal of the action as a victory as it was able to stand by its policy of affordable health care without having to sacrifice the international trade treaties that it was party to. It was a hollow victory though in that the issues that were at stake were central to a free market economy. The withdrawal of the action allowed the SA government to pursue its policies and the MRSCA Bill was promulgated in 2002.

The prohibition on sampling and the removal of incentives and bonuses by the pharmaceutical industry automatically kicked in with promulgation. The Government moved speedily to set up the Pricing Committee whose job it was to include the gathering of pharmaceutical intelligence in order to advise the Minister of Health on a transparent pricing system for medicines. It also activated the system of generic substitution which had been endorsed by all medical aid schemes.

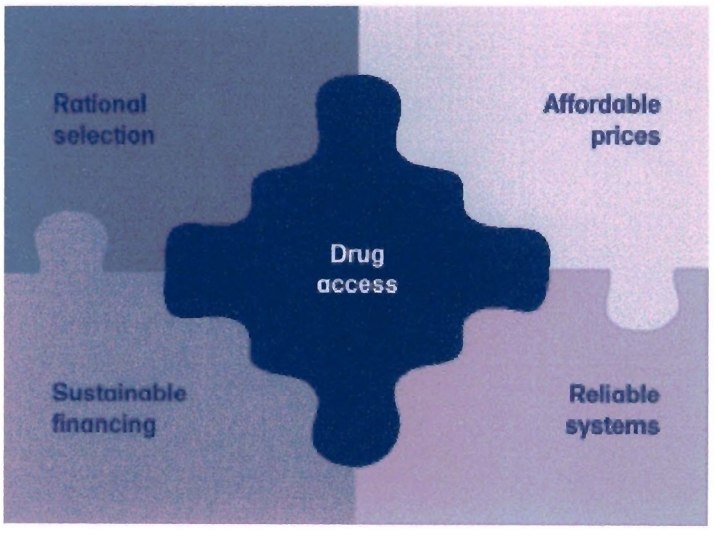
The SA government pledged to engage the pharmaceutical industry in the local context and in the international arena as there was a growing realization internationally that governments could not tackle the major public health problems of developing countries without concentrating all available resources. This demanded a new style of commitment by government to venture into partnerships with the private sector and a joint working group with the pharmaceutical industry was formed to consult on and consider broader issues in the area of health care. Government felt that this was the way forward in holding multinational companies accountable for the markets they dominate.

3.2 THE ECONOMICS OF PRICING IN THE PHARMACEUTICAL INDUSTRY

Any government wishing to pursue equity as a policy goal will commit itself to improving access to quality health care. Economic factors that constrain this access are usually related to the costs of services. In South Africa, out-of-pocket expenditure is high, as is the case in the rest of the developing world. In sub-Saharan Africa figures range as high as 65% of total drug expenditure, in Asia 81%, while it is less than 40% in established market economies (Internet 9). Drug prices can therefore be considered a

crucial element in determining access to health care therefore drug costs impact directly on policy choices of government especially in the public sector. The cost of drugs is a prime consideration in whether or not they are included in Essential Drugs Lists, both internationally and in South Africa. Cost alone does not determine access as depicted in Figure 2.1 (Internet 9).

Figure 3.1: INTERLOCKING CONTRIBUTIONS TO DRUG ACCESS



Source: WHO/EDM staff

3.2.1 South African public sector expenditure and prices

Drug acquisition costs either to patients or health care systems are a major part of recurrent costs. In the South African public sector, drug costs are second only to personnel costs. Data on actual consumption in the State sector is patchy but historical data available to the Department of Health Chief Directorate: Pharmaceutical Services is shown in Table 2.1. The industry estimate of total public sector purchases in 2000 was R1.96 billion (Internet 9)

Table 3. 1: Provincial expenditure on drugs per financial year

Province	1994-95	1995-96	1996-97	997-98	1998-99	1999-2000	2000-01
Eastern Cape	N/A	N/A	N/A	N/A	N/A	*78.646*	N/A
Free State	N/A	N/A	N/A	N/A	N/A	104.607	*61.390*
Gauteng	N/A	N/A	380.418	451.274	468.430	*352.314*	*453.499*
KwaZulu-Natal	188.995	207.600	274.523	284.630	251.948	296.459	*310.000*
Mpumalanga	N/A	N/A	N/A	N/A	N/A	*103.000*	N/A
Northern Cape	N/A	N/A	N/A	N/A	N/A	41.148	N/A
Northern Province	N/A	N/A	123.260	126.276	127.670	146.319	*149.000*
North West	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Western Cape	112.68	157.401	170.358	190.977	209.544	216.209	*201.411*

Notes: Actual expenditure is stated, where available. Where only budgets were available, these are indicated in italics. North West reported that drug expenditure could not be separated from the other items under Standard Item C (Stores and Livestock), but that payments to the Gauteng depot for 1998-2000 totaled R72.647 million, and to other suppliers for the period 1997-1999,R13.164 million. The SA Military Health Services also budgeted R100 million for drugs in the 1999-2000 financial year.

N/A=not available

Sources: National Department of Health and individual provincial Heads of Pharmaceutical Services

3.2.2 Private sector spending: medical aid expenditure

In the private sector, drugs are the single biggest cost driver. The Registrar of Medical Schemes reported that out of expenditure of a total of R18.745 billion paid out by medical aid schemes in 2000, medicines accounted for 27%. However, of the 28.5% of payments that were made to private hospitals, some were also for drugs used by inpatients and those that were issued as discharge medication. Per capita expenditure on drugs in the public and private sectors are thus markedly different. The sales figures for

2001 quoted by the Pharmaceutical Manufacturers Association (PMA) put the total value of anticipated drug sales to be R12.25 billion of which public sector sales were 24%, which implied a per capita expenditure of about R 60.00. In contrast, the per capita expenditure on prescription drugs in the private sector was R800.29, excluding sales of over-the-counter (OTC) medicines, which constitute only 6% of the total value. This includes sales via private pharmacies, private hospitals and dispensing doctors, who are responsible for 15% of drug sales. If the dispensing doctors are servicing only indigent patients on behalf of the State as is claimed, the private sector per capita expenditure would still be R641.69, which translates to more than 10 times the amount spent per person in the public sector (Internet 9).

3.2.3 The cost of drugs in South Africa

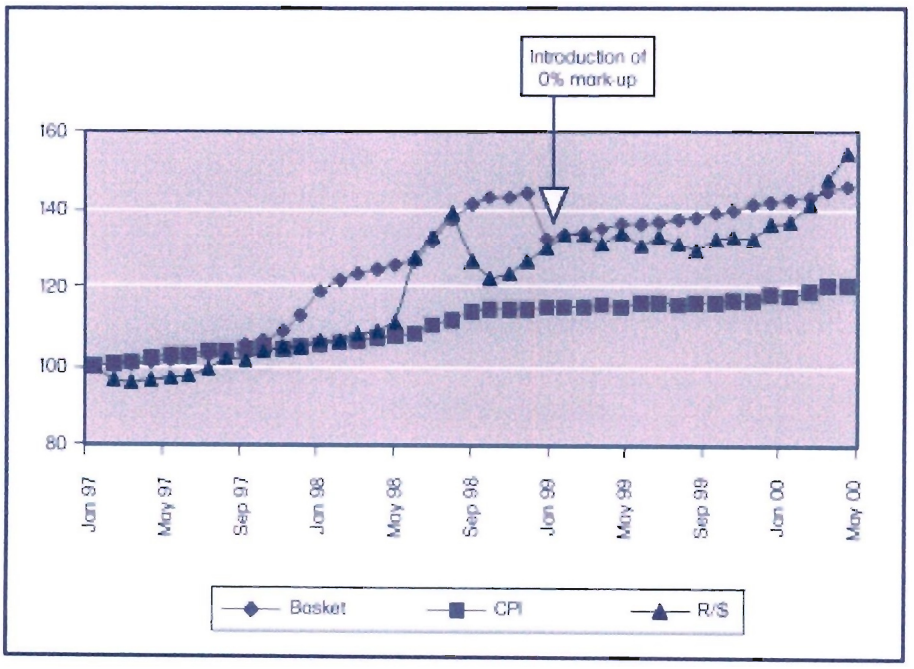
The cost of drugs in South Africa relative to other markets has long been a contested issue. In 1997 government statements on the matter were the subject of a complaint by the PMA to the Public Protector. One of these alleged "offending statements" was that "South Africa rated in the top five most expensive countries in the world for medicine". The final ruling by the Public Protector is perhaps indicative of the complexity of the subject. He stated that it was "not possible to say that the Minister of Health was able or unable to prove or substantiate the statement". However, he went on to record his view that "pharmaceutical profits are substantial in this country; that the cost and price of pharmaceuticals in South Africa is high; and that the amount spent on medicine, is nearly double to triple that of other major countries". This area of policy has also been seen as part of a greater struggle, one that pits the health and economic interests of the South against those of global free trade (Internet 9).

The National Department of Health does not routinely collate price comparisons over time. However, in preparation for the tender adjudications in 2001, a comparison was made of a selected basket of high expenditure items. According to DOH figures, for 31 of the 36 items, prices for the same pack sizes could be compared between 1997 and 1999. The median price change was an increase of 7.8% per annum. While the largest increase was 93.2% pa, the item with the greatest price decrease dropped by 7.5% pa. For the 22 items for which a 2001 price was available, the median change from 1997 was an increase of 7.4% pa. The largest increase was 62.1% pa, and the item with the

greatest price decrease had dropped by an average of 13.9% pa (Internet 9).

The Hospital Association of South Africa monitored the prices of a basket of 1 000 high cost/high volume items, which were compared to the prevailing consumer price index (CPI), and tracked against the Rand-US dollar exchange rate. Against a January 1997 index of 100 for each parameter, the all products basket reached 145.9 in May 2000, whereas the CPI was only 120.4. The rand had weakened to 154.1 by the same point. The close tracking of the exchange rate and the basket price is shown in Figure 2. 2.

Figure 3.2: Prices of a basket of 1 000 drugs used in private hospitals, plotted against the consumer price index (CPI)and Rand/US dollar exchange rate



Source: Hospital Association of South Africa

It should be noted though that expenditure is a result of both unit price and volume of consumption. As a reference point, the United Kingdom, with the highest prices in Europe, managed to keep drug expenditure to about 10% of total health care costs (Internet 9).

3.2.3.1 Price surveys

The PMA and the Minister of Health's price comparisons are clearly at variance with each other. This is because the entire area of pricing assessments is fraught with methodological difficulties. Among the issues shown to have considerable effects on

the results of surveys that attempt to compare prices over time or between countries are:

- Sample selection :it may be necessary to include generics and OTC drugs that might substitute for the branded items being compared
- Units of measurement for price and volume: often pack sizes vary considerably, and direct comparisons between bulk and patient-ready packs cannot be made on the basis of unit dose prices
- The relative weight given to consumption patterns in the different settings
- The use of exchange rates or purchasing power parities for currency conversions (Internet 9)

Despite methodological concerns, policymakers continue to act on studies that display weaknesses. A study that sought to compare South African prices with those in known high price countries like USA, UK, Germany, Denmark, Netherlands, is still used by the PMA today to ratify pricing decisions. Price comparisons between countries and the public and private sector continue to make headlines. At present there is no internationally acceptable reference pricing system. The current International Drug Price Indicator Guide produced by Management Sciences for Health has been attacked from various quarters. It is a listing of prices from supply organizations that service non-profit humanitarian projects and government bulk-purchase structures but lacks quality of data with regard to the suppliers (Internet 9).

In South Africa, there are considerable differences between private sector prices and those offered on State tender. Claims are made that the difference is on average 10-fold. It is alleged that the lower prices offered to the State are responsible for higher than usual prices in the private sector, in other words that higher private sector prices are used to offset revenue losses and that this constitutes cross-subsidization. There are no accurate data to support either contention. There is also evidence of discriminatory pricing practices between different purchasers in the private sector (Internet 9).

An in-depth Competition Board investigation concluded that such discriminatory practices existed, that they constituted a "restrictive practice", and that this was not in the public interest (Internet 9). Some of these practices, such as the selling of stock by dispensing practitioners to so-called "short-line" wholesalers have been dealt with by

the Medicines and Related Substances Control Amendment Act (Act 90 of 1997). The Act prohibits wholesalers from buying drugs from anyone other than a manufacturer or importer. This type of in-country market segmentation is not unique to South Africa, and has also been demonstrated in the United States (Internet 9).

3.3 THE DOH'S DRUG POLICY

The DOH's drug policy is founded in the National Drug Policy that was developed in 1996. As early as mid 1994, the then newly constituted Drug Policy Committee was tasked to "develop a pricing plan for drugs in South Africa in the public and private sectors" (Internet 5). The resulting drug policy's stated aim was to ensure the availability and accessibility of essential drugs to all citizens with the added economic objective of lowering the cost of drugs in both the private and public sectors. It also aimed to promote the rational use of drugs, thus targeting both parts of the expenditure equation. As a national development objective, the Committee supported the development of the local pharmaceutical industry and the local production of essential drugs (Internet 9).

Specific cost containment measures that were part of the policy development included:

- A pricing committee, to "monitor and regulate drug prices"
- Total transparency in the pricing structure at all points of the distribution chain
- A non-discriminatory pricing system
- Replacing the wholesale and retail mark-up system with one based on a fixed professional fee
- A database to monitor costs compared with other developing and developed countries
- Regulation of price increases
- Provision, in certain circumstances, of public sector stock to the private sector
- Promotion of generics products including the policy of generic substitution, while maintaining a negative list where the prescribed brand had to be supplied
- Measures to improve rational drug use, including establishing Pharmacy and Therapeutics Committees (PTCs) in all hospitals and
- Control of pharmaceutical marketing practices (Internet 9).

International tendering, competitive negotiation for state supplies and price preferences for local manufacturers was included in the DOH's procurement policy. Export of local products to neighbouring countries was supported. Many of these measures have been promulgated with the MRSCA legislation.

3.3.1 The economics of drug policy options

Medicines are not ordinary articles of trade. Specifically, their demand and supply characteristics do not follow classic market principles. There is a three-tiered demand structure: prescribers, including physicians and others, as the actual demanders, the patients as the consumers and the health care system frequently the payer in both the public and private sectors. There is often limited competition between suppliers, especially in the case of patented products. Medicines also have both positive and negative externalities as is the case with treatment of TB, which benefits that patient and reduces the spread to the community (Internet 9)

.

A case can be made then for government intervention with policy in that information available to prescribers and consumers is often selective, unbalanced or incomplete, further demonstrating the supply-driven nature of trade in medicines. Also, market forces rarely reflect true social costs and benefits, and cannot meet social objectives such as equity. The factors mentioned above could constitute a situation of market failure, where drugs can therefore be considered to be "meritorious" goods, worthy of government intervention (Internet 9).

The pharmaceutical industry begs to differ. Industry groups claim that the market is working, that interventionist policies don't work and actually increase health-care expenditures, and stifle innovation. The global industry would prefer a situation of market pricing for all medicines, less dependence on national social security systems, more private/insured purchase, and competitive purchasing systems operating in a price-deregulated environment. In fact, there have been calls to adopt US standards even to the point of having direct-to-consumer advertising (DTCA) of prescription drugs. A recent policy analysis of DTCA options for South Africa commissioned by the DOH has suggested retaining a European rather than US standard (Internet 9).

3.3.2 Government interventionist policies

Governments that choose to intervene in drug policy can be characterized in a number of ways. They can be either direct via primarily legal measures that have an immediate effect on suppliers or consumers or indirect using usually market-related measures, which entail financial implications for the players. Governments may also either target prices themselves with supply side measures such as price controls, positive or negative lists, and promotion of generics or consumption via demand side measures such as exclusion from positive lists, reclassification to OTC status, introduction of patient co-payments and caps on pharmaceutical budgets (Internet 9).

Policy options exercised by governments have resulted in either a total control situation like in Ecuador and Honduras, a mixed system similar to that of Canada, monitored freedom like in Brazil or total freedom as in the US. Price control policies are more common in developed than in developing countries, even though price sensitivity might be greater in countries with poorer social security systems (Internet 9).

While the South African government's policy commitment to some form of intervention is clear, the exact mechanics of the proposed system are still being formulated. Policy instruments available to government include:

- Producer price control measures with direct price controls, reference pricing systems, equity pricing and generic policies
- Distribution chain cost controls of mark-ups and fixed professional fees
- Bulk purchase measures using tender and negotiation strategies and regional initiatives in the SADC region
- International trade agreement relief measures with compulsory licensing and a policy allowing parallel imports
- Demand side measures that involve rational drug use and co-payments by consumers (Internet 9).

3.4 THE RELATIONSHIP BETWEEN STAKEHOLDERS

In the above discussion, policy options available to the South African government have been explored. The reality is that this is a dynamic environment that involves a

relationship between all stakeholders, the pharmaceutical companies, government, suppliers of service and consumers represented by medical aid schemes. It is important to consider then the pros and cons of policy options and their impact on the various stakeholders.

3.4.1 Producer price control measures

The imposition of direct price control is in conflict with South Africa's national trade and industrial practices, which are influenced to a large extent by global trends. The balance of evidence from other countries would seem to indicate that such practices, while commonly used, are complicated and easily circumvented by transfer pricing via inflation of the prices of imported raw materials. This policy is also open to political interference, and relies to a great extent on industry transparency. Further, production costs are not often easily determined, while the use of a landed costs plus system is open to manipulation by transfer pricing (Internet 9).

A more transparent system is that of reference pricing. Internal reference pricing systems involve a national authority setting local prices for a drug by comparison with similar drugs on the national market. External reference pricing systems use the prices of drugs sold in other countries as well, as part of the comparison. In South Africa, a form of this system is already in effect in the private sector, where many medical aids use a maximum medical aid price (MMAP) system for drugs that are no longer controlled by a patent and are therefore available from many sources. Patients who wish to receive a branded version that costs more than the MMAP have to pay the difference in price themselves. However, it is unclear whether any such system is applied when adjudicating State tenders. International experience in the Netherlands and Germany has been that reference pricing is not effective, and is out-flanked by changes in prescribing habits. It also shifts the load to the patient, by way of the additional co-payments that are necessary. Innovator drugs are usually not covered by reference price systems, as no comparator products exist. If applied internationally, this might result in convergence of prices at higher levels, hurting current low price countries (Internet 9).

Equity pricing may be a favoured option, where manufacturers agree to subsidize lower prices in developing countries by levying higher prices in wealthier countries. Two

potential problems with this approach are that prices might not drop sufficiently or consumers in the Northern hemisphere might insist on either lower prices or the right to import drugs from low price countries. Legislative attempts to allow such parallel trade are already underway in the US. Equity pricing is the basis for the UNAIDS negotiations with major AIDS drugs manufacturers, and also underlies offers of drug donations to developing nations. Neither approach is without problems. Donations in particular are difficult to accept when accompanied by demands for additional monitoring and systems costs and restrictions, as was the case with the Pfizer offer of fluconazole to South Africa in early 2000 (Internet 5).

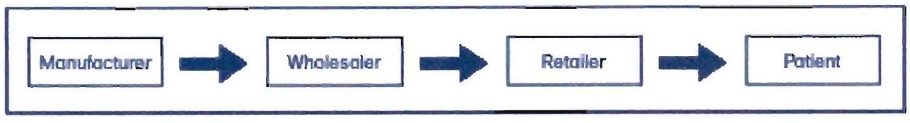
Efforts to promote the production and use of generic medicines, while unpopular with the research-based industry, are effective. They stimulate competition and promote the development of local manufacturing concerns. Two policy instruments to facilitate this process are however lacking in South Africa. The first is an unambiguous legal framework for generic substitution, which is already practised in the public sector, and is often necessary in order to comply with MMAP restrictions in the private sector and secondly policy that will allow prospective generic manufacturers to complete scientific and regulatory processes before the expiry of the patent, allowing for quick entry of the generic product onto the market and fair competition with both the originator product and any "generic" versions made by that company or its subsidiaries. Such provisions are not in conflict with international trade agreements but this practice is not welcomed by industry groups. The most dramatic evidence of the impact of generic competition on drug prices has been provided by Brazil where anti-retrovirals that were only available from innovator companies reduced in price by only 9% from 1996 to 2000, whereas the prices of those that did face such competition dropped an average of 79% over the same period (Internet 9).

3.4.2 Distribution chain cost controls

PMA contentions are that South Africa's distribution chain costs are among the highest in the world, adding more than 100% to the manufacturer's factory gate price (Internet 1). This is vehemently denied by the Pharmaceutical Society of South Africa (PSSA). Direct control over mark-ups has been abandoned by government, but is still exercised indirectly by the reimbursement policies of the medical aid industry. The traditional

distribution route for pharmaceuticals in the private sector is illustrated in Figure 3. 3.

Figure 3. 3: Traditional distribution chain for medicines



Note: the "retailer " is either a pharmacist in a retail pharmacy or private hospital or a dispensing doctor. SOURCE: www.napm.co.za

At each step a percentage mark-up is applied, but this is also often accompanied by a discount. The actual mark-up might therefore be lower than the theoretical figure. However, each stage starts from a presumed price resulting from application of the theoretical mark-up by the previous player. In most cases, patients do not pay directly for their medicines. Payment is rendered by the medical aid, which is therefore a third party to the transaction between the seller (pharmacist or doctor) and the supposed buyer (the patient). The mark-ups are to a large extent the result of acceptance of the system by the payers, the medical aids. This acceptance is formalized in the Pharmaceutical Scale of Benefit published by the Board of Healthcare Funders (BHF), which is a voluntary association of medical aids. Most medical aids make use of intermediaries, medical aid administrators like Medscheme, to manage the payments for claims submitted by their members (Internet 9).

The start of the process is the manufacturer's selling price, also called the factory gate or exit price. Theoretically the pharmaceutical wholesalers add a mark-up of 21.2%. However this is brought down by the practice of giving retail clients discounts, either on bulk purchases or as reward for loyalty based on the total of that client's purchases over a period of time. These discounts average 10-11%. The retail pharmacy sector adds a 50% mark-up on the theoretical wholesale exit price. This results in a maximum 81% mark-up from manufacturer to patient (Internet 1).

Additional dispensing fees (R1.20 per item), broken bulk (10%), container and copy fees add negligible amounts to the final bill. However, third party payers demand discounts from the retailer, varying from 20% for acute medication to 30% for chronic

medication. This can be confirmed by looking at the average cost difference between gross amounts claimed and net values paid by medical aid administrators. In 2001, this difference amounted to an average of 23.8% for one such administrator (Internet 1).

In order to understand the net result of these mark-ups and discounts, it is easier to consider a product leaving the manufacturer at a nominal R100.00. This product would therefore be sold by the wholesaler at R121.20, but the discount offered would on average reduce the actual cost to the retailer to R109.80. The retail pharmacist would then add the 50% mark-up to the theoretical purchase price of R121.20, selling the product at R181.80. In turn, the retail pharmacist would be required to discount this price to either R165.25 (20%) or R145.08 (30%) depending on whether it was claimed against the patient's acute or chronic benefit. Value added tax would be levied at 14%.
If the actual amounts retained by each actor in this chain after applying discounts are expressed as percentage contributions to a final amount (100%), for each of the two discount scenarios described above, then the "contribution" of each step to the final cost can be seen Table 2.2 (Internet 9).

Table 3.2: Relative contributions to the final selling price of a medicine to the private sector patient in South Africa

Discount scenario	Manufacturer exit price (%)	Wholesale mark-up (%)	Retail pharmacy mark-up (%)	VAT (%)
20% (acute medicines)	60.5	5.5	21.7	12.3
30% (chronic medicines)	68.9	6.3	12.5	12.3

Source: www.napm.co.za

The greatest proportion of drug costs is accounted for by the manufacturer's exit price, with less than 40% being constituted by the entire distribution chain costs. There has been significant vertical integration in South Africa. As much as 55% of wholesale trade now goes through direct distributors owned by consortia of manufacturers, like Direct Medicines (Internet 1).

The situation in South African private hospitals is different, where a 0% mark-up on wholesale list price is levied. Private hospital pharmacies have however been able to use their collective buying power to extract rebates from manufacturers of up to 20%. In effect therefore, they make a profit on medicines despite levying no mark-up. When the 0% mark-up was introduced, an agreement was reached between the hospitals and the medical aids that prices should not rise more than 20% between December 1998 and April 2000. They had in fact only risen by 13.2% over that time period, as can be seen in Figure 3.2. Nonetheless, a steady increase in private sector drug prices is evident from the data (Internet 9).

The DOH objective of replacing mark-ups with a fixed professional fee has not been realized, despite intense negotiations between the PSSA and BHF. Current proposals include a professional fee of R20.00 per item, plus the disclosed non-discriminatory net unit exit price from the manufacturer, plus inventory related costs (5%) and practice costs (R4.00). No discount would be given to the medical aid, and VAT would be levied as before. However, as this fee would be applied regardless of the cost of the medicine, current very low cost items might actually increase in price. The logic behind the policy is that removing the profit motive will mean that the pharmacist earns the same amount, regardless of whether there is dispensing of an expensive branded product or a cheaper generic. One effective cost containment measure that is in place is that for anti-retrovirals under the "Aid for AIDS" programme operated by Medscheme. Such drugs are paid for by the medical aids at factory gate prices plus R50.00, without any mark-ups at either wholesale or retail level. However, this does not apply to other AIDS-related drug needs, such as drugs for opportunistic infections and palliative care (Internet 1).

3.4.3 Bulk purchase measures

The State already uses the most basic measure, that of competitive bidding by a tender system, as the major mechanism to ensure maximal price leverage. However, tenders are only open to locally-registered firms. It is possible that better prices might be obtained on the international market. This does have implications for the reach of the Medicines Control Council (MCC).

Manufacturers abroad should either be cleared by the inspectorate for Good Manufacturing Practice (GMP) standards, both before and during the tender period, or foreign regulatory systems or international certification schemes must be relied upon to guarantee the quality of goods purchased. Recent indications are that competitive bidding alone is not assuring the State of sufficiently competitive prices. A number of products were identified where the price offered by a local tender was more than double the median price in the International Drug Price Indicator Guide (Internet 1).

Post-tender negotiations have been successfully used to further reduce prices in some instances. A growing demand is for regional bulk purchasing arrangements, particularly with other member states of the Southern African Development Community (SADC). These are crucial if African countries are to overcome their historical disadvantage in negotiating power with the global pharmaceutical market. Such arrangements can also be used to bolster local production. Africa still imports more than 90% of its pharmaceutical needs, and the African share of global production value has slipped from 1.3% in 1975 to 0.7% in 1995. Three successful regional schemes are available for comparison. Bulk purchasing by countries of the *Union Maghreb Arabe* (Libya, Mauritania, Tunisia, Algeria, and Morocco) achieved price reductions ranging from 15-20%. The six-nation Gulf Cooperation Council (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) achieved savings averaging 30%, compared to purchasing by individual countries. A trial by the African Association of Central Medical Stores for Essential Drugs (ACAME) involved 5 essential drugs procured by three countries (Guinea, Mali, and Niger), compared to bulk purchasing tenders. The costs obtained by the bulk scheme were 7-27% lower than the individual countries had been able to obtain for the previous 3 years (Internet 9).

Perhaps the most telling evidence of the power of collective bargaining comes from the recent MSF price comparison study which noted that far greater reductions had been obtained by international agencies with regard to drug price reduction offers to African agencies. The Pan American Health Organization (PAHO) supplies vaccines at discounts of between 86 *(Haemophilis influenzae* type B) and 99% (oral polio vaccine) compared to US public sector (Centers for Disease Control) prices. The United Nations

Population Fund (UNFPA) is able to supply contraceptives at between 97% (injectables) and 99% (condoms and oral contraceptives) discounts compared to US wholesale prices (Internet 9).

3.4.4 International trade agreement relief measures

A fundamental way to address prices would be to weaken the monopoly-like powers afforded the manufacturers by the patent system. In essence this would involve either or both of the following measures:

- Compulsory licensing by giving a local firm the right to make a copy of an expensive patented drug at a lower price, while compensating the patent holder
- Parallel importation by buying drugs from countries where prices are already lower, and so trading in parallel with the local seller of the same drugs.

Patent rights are underpinned by international trade agreements, in particular the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). For example, by 2006 all signatories to the Agreement, which means all members of the World Trade Organisation, must give drug companies 20 years' patent protection on their inventions. Much attention has therefore been focused on attempts to soften the potential access-denying impacts of these agreements. The WHO and other commentators have produced guidelines on the safeguards available to nation states under the TRIPS agreement. Opposing views on such measures include the view that a patent is not an absolute right (Internet 5).

Included in the relief measures outlined by the WHO, and in line with the international agreements, is the right to issue compulsory licenses. This right may be used where a patent holder can be shown to be abusing its monopoly position, or in cases of national emergency. Such licenses may only be used predominantly for supply of the domestic market, but both entire imports and partial exports are permissible. This could allow South African decisions to be made to the additional benefit of our SADC neighbours.

A compulsory license issued in South Africa could be used to allow importation of the drug that was the subject of the license from a manufacturer outside of South Africa.

However, while the TRIPS agreement only allows this strategy to be used to mainly satisfy our own needs for the drug, there is some flexibility allowed. Some of the stock procured under the license, by local manufacture or importation, could in turn be exported. Such flexibility is important if South Africa is to export needed drugs to neighbouring countries, which perhaps lack the infrastructure to engage in manufacture under compulsory licenses. South Africa has recourse to the 1978 Patents Act, which includes a compulsory license provision. The Medicines Amendment Act (Act 90 of 1997) introduced health-specific measures to exploit the safeguards provided by TRIPS (Internet 5).

Parallel importation is based on the principle of exhaustion of rights, a patent holder's rights are said to be "exhausted" once the product is first placed on the market, allowing the purchaser to resell the product without offending the intellectual property rights of that patent holder. Specific mention is necessary in national law of where rights are considered to be exhausted, so that parallel trade can occur within that area. Industry groups have contended that even where regional exhaustion of rights does occur, as in the European Union, price reductions to the consumer have been modest. It is alleged that profits are generally retained by the parallel importer. This might not be the case where the State is the importer, but might blunt the impact of parallel trade in the private sector. There is a concern that parallel trade and price regulation based on international comparisons might lead to price convergence at higher levels (Internet 9).

Many developing nations assume that innovator products are patented in their countries. It is important to note that international patents do not exist. Patents are only issued in terms of national law or regional agreements. Some countries and regions have mistakenly enacted patent measures in excess of the minima set by the World Trade Organization (WTO). This is particularly true of the West African signatories to the revised Bangui Agreement. South African health authorities have also not made a systematic search for unpatented products, which might be available cheaper from generic manufacturers such as those in Brazil and Thailand. A major feature of the global pharmaceutical industry is that of voluntary licensing, to a greater extent than is seen in other manufacturing sectors. Cross-licensing between firms that have shared R&D costs is also common. This experience can be put to good use in technology

transfers between major multinationals and local manufacturers, without unduly impacting upon global returns on investment (Internet 9).

3.4.5 Demand side measures

Coercive rules to force rational prescribing behaviours on prescribers have rarely been successful without considerable "buy-in" by the prescribers. This remains a neglected area in both the private and public sectors in South Africa. The SAMA has attempted to address the situation by developing minimum treatment guidelines for medical professionals, to set a minimum standard of cost-effective care in South Africa. The dispute over licensing of dispensing doctors has not helped the situation as medical professionals felt marginalized in favour of pharmacists, by government.

3.5 THE MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, ACT 59 OF 2002

This Act provides for the supply of more affordable medicines to the people of South Africa, and for the tightening up of safety regulations concerning the manufacture, preparation and dispensing of medicines in South Africa.

3.5.1 The Supply of Medicines in South Africa

Under the previous legislation, only medicines registered in South Africa could be imported and supplied to pharmacies, hospitals and patients. It was not possible for pharmacies to obtain or dispense 'generically equivalent' medicines - medicines which contain the same active ingredients and are identical in dose or concentration and dosage form to the registered, branded medicines, but which are usually considerably cheaper.

3.5.2 Parallel Importation

The Act allows the 'parallel importation' of medicines, which means buying an identical product made by the same company, but from a location other than where the South African distributor purchases it, and at a lower price. It is also permissible to import medicines not currently registered in South Africa if they are generically

equivalent to medicines already registered in South Africa. The South African government justified this position by stating that it recognizes the intellectual property rights of manufacturers of patented medicines and will only parallel import from countries and companies which also recognize patent rights and which include the accepted patent cost in the overall price of the generic equivalent medicine.

3.5.3 Prescribing Generically Equivalent Medicines

Doctors and other health professionals issuing prescriptions are encouraged to prescribe generically equivalent medicines, instead of branded medicines. Moreover, whenever a person takes a prescription to a pharmacist, the pharmacist will have the following obligations:

- to inform the person of the benefits of substituting the prescribed medicine with a generically equivalent medicine
- to dispense a generically equivalent medicine, instead of the medicine prescribed, unless expressly forbidden to do so by the patient.

A pharmacist will not be permitted to dispense a generically equivalent medicine if:

- the person prescribing the medicine has written 'no substitution' in his/her own handwriting on the prescription
- the retail price of the generically equivalent medicine is higher than that of the prescribed medicine
- the product has been declared unsuitable by the Pharmacy Council of South Africa.

3.5.4 Pricing Committee

A pricing Committee was established to advise the Minister on a transparent pricing system for all medicines, to monitor the pricing of medicines and advise on an appropriate dispensing fee.

3.5.5 Bonusing and Sampling

Bonusing is an incentive system used by pharmaceutical companies to encourage pharmacists or other licensed dispensers to supply their medicine in preference to another. Sampling is a system under which manufacturers, wholesalers or agents supply free medicines to pharmacists or other licensed dispensers.

Both bonusing and sampling was banned, as is any other rebate system or incentive scheme. This is an attempt to eradicate any perverse incentive schemes which have impacted on ethical health care delivery.

3.5.6 Code of Ethics

A code of ethics is to be implemented by the Minister relating to the marketing policies of pharmaceutical companies after a consultative process with all stakeholders.

3.5.7 Safety Regulations

With the change in legislation, the SA government aimed to improve safety and time efficiency, therefore it now:

- requires that medical practitioners, dentists, practitioners, nurses and any other registered person be licensed before being allowed to dispense medicines with the exception of an emergency bag containing medicines to treat patients in emergency situations, which will not require a dispensing licence
- requires that manufacturers, wholesalers and distributors of medicines or medical devices to apply to the Medicines Control Council for a licence before being allowed to manufacture or supply such medicines or medical devices
- increases the powers of inspectors to enter any premises in which medicines are manufactured, stored, compounded or dispensed; and to enter any premises, place, vehicle, vessel or aircraft if there is reason to suspect that an offence has been or is being committed or attempted.

3.6 THE HEALTH PROFESSIONALS COUNCIL'S RESPONSE

The HPCSA responded to the legislative changes by issuing guidelines regarding perverse incentives that supplemented its existing policy. These policy guidelines were translated by SAMA
into a Code of Ethics that should govern the relationship between the medical fraternity and the pharmaceutical industry.

The HPCSA stated that "health care professionals should always try to avoid potential conflicts of interests and maintain professional autonomy and independence. Any

conflicts of interests or incentive or form of inducement which threatens such autonomy, independence or commitment to the appropriate professional and ethical norms or which does not accord first priority to the clinical need of a patient, is unacceptable" (Internet 7).

In this policy statement, the Medical and Dental Professions Board identified those incentive schemes and forms of inducement which it finds unacceptable but acknowledged that this should not in any way be regarded as an exhaustive list. The principles underlying the listed perverse incentives however, would be will applied in every case of alleged unprofessional conduct on the part of a health care professional in the private or public sector and where applicable would form the basis for an investigation by an appropriate health care authority or the Board (Internet 7).

The HPCSA acknowledge that historically, there has been a close collaboration between health professionals and the pharmaceutical and health supply industry which extended particularly to continuing professional development. However, it felt that health care is to a large extent self-governing and practitioners were encouraged to ensure that their participation in such collaborative efforts was in keeping with their duties towards patients and society. Although the decision on content and choice of continuing professional development activities, as well as funding arrangements lay ultimately with the health care provider, organisations such as professional associations, its branches and groups, should not be put in a position of conflict of interest by virtue of any relationship with the funding body. The organisers may acknowledge financial or other aid received, but should not identify any specific products. Generic names of products should be used rather than trade names in the course of continuing professional development activities. Funds for continuing professional development activities should preferably be in the form of an educational grant payable to the health care provider organisation arranging the activity (Internet 7).

The HPCSA felt that no travel or lodging costs or other expenses should be paid by the industry for individual health care professionals to attend a continuing professional development event. Scholarships, grants or other special funding, to permit students and other deserving health care professionals to attend continuing

professional development activities are permissible, provided the funds are paid to the organizers for disbursement. The organizers may extend reasonable honoraria and imbursement for travel, lodging and meal expenses to speakers. The principal event should at all times centre around education and not around meals, entertainment or other hospitality, the cost of which should not exceed that level which the recipients might reasonably be expected to incur for themselves under similar circumstances (Internet 7).

The HPSCA supported the established practice that health professionals should benefit from being exposed to new knowledge and insight into their respective professions and/or disciplines by the attendance of international conferences, either locally or overseas. It was regarded of utmost importance that young and upcoming health care professionals and educators and those from disadvantaged backgrounds be given an equal opportunity to expand their knowledge and understanding with regard to their respective professions and/or disciplines by the attendance of such international conferences. It was therefore permissible for companies to sponsor delegates to attend international conferences, either directly or through professional associations/societies, with the proviso that a fair and transparent process should be followed in the election and sponsoring of delegates to attend such events, especially with regard to the attendance of such conferences by young and upcoming health care professionals and educators and those from disadvantaged backgrounds.Such sponsorships were to be earmarked for specific educational events/conferences and not for holiday purposes (Internet 7).

It was stressed that a distinction should be made between education and training on the one hand and product promotion on the other as practitioners could not be seen to be earning continuing professional development points for attending product launches or other product promotion events.

3.7 THE IMPACT OF NEW LEGISLATION ON PHARMACY PRACTICE

The Pharmacy Act came into effect on 2 April 2003. This deregulated pharmacy ownership in South Africa. Pharmacies could now be owned by non-pharmacists so long as a qualified pharmacist is employed to run them. This mirrored the situation in

the United Kingdom and it opened the door for multiples and other retailers to increase their representation. For example, mixed supermarket style retailers like Pick n' Pay could enter the market.

Under the new act the South African Department of Health (DOH) will have responsibility for the licensing of pharmacies. All persons wanting to own a pharmacy, including registered pharmacists, have to apply for a licence. By having control of pharmacy licensing, the DOH obtained a more rational distribution of pharmacies. There was no guarantee that, should a pharmacist wish to sell an existing business, a licence will be transferred to a new owner. It depended on whether the DOH found it favourable or not and the DOH was likely to consider the siting of the existing pharmacy in its decision.
The South African Pharmacy Council continues to have responsibility for the registration of pharmacists. This includes maintaining acceptable standards in pharmaceutical education and pharmacy practice. With regard to pharmacy premises, the pharmacy council's role is limited to inspection and record keeping only.

United South African Pharmacies, which represents about two-thirds of independent community pharmacies in South Africa, has expressed concern about the possibility of large retail firms stepping into pharmacy. It has suggested that large retailers should only be permitted to open up pharmacies in areas that do not currently have pharmaceutical services. There appears to be some uncertainty about the DOH intentions with regard to this.

In the Medicines and Related Substances Control Amendment Act, Act 90 of 1997, pharmacists are required to offer customers a generic substitute, regardless of what the prescriber has written. This is assuming that the drug is off-patent and a generic is available. The aim of this according to the director-general of health, Ayanda Ntsaluba, is that Act 90 will bring down drug costs.

Concerns have been raised that this legislation, although aimed specifically at amending practice in community pharmacy, will have implications for hospital care. Norman Weltman, director of the Hospital Association of South Africa, has questioned how pharmacists are expected to deal with an unconscious person since

the new legislation specifies that patients must be asked whether they would like to receive a generic substitute.

3.8 DEFENDING THE MEDICINES CONTROL AMENDMENT

This Act was enacted during the term of President Nelson Mandela who was cited as the first respondent. It was a critical instrument seen by the SA Government as a way of achieving its National Drug Policy (NDP).

The SA government's motivation for the changes in legislation were:

- The legislation was viewed as a major step forward in the drive to improve South Africa's access to cheap, safe, quality medicines.
- The cost of medicines to patients, hospitals and medical aid providers was being cut.
- It was felt that the pharmaceutical companies opposed the Bill, because it reduced their scope for profits, however, the South African medical aid industry welcomed the Bill, because it reduces costs to patients.
- The discredited practice, employed by some pharmaceutical companies, of providing free samples, bonuses, perks and even free holidays to medical professionals for prescribing and dispensing their drugs was dealt with.
- The DOH would be able to use savings on the cost of medicines to improve other aspects of health care delivery.
- The Bill, for the first time, gave patients a real choice in what medicines they are being prescribed.

3.9 PHARMACY ACT 90

Pharmacy Act 90 is a progressive piece of legislation that aimed to regulate the pharmaceutical industry while offering the SA government some comfort that the people of South Africa were going to benefit in terms of affordability of pharmaceutical products. After 1994, South Africa was viewed as a positive market to enter for most multinational companies, however, there was also the reality that a 'black market' in trading of most commodities was also open and the pharmaceutical industry was not immune to the attack from cheap, parallel imports from developing countries. Section12 of Pharmacy Act 90 has two controversial areas.

3.9.1 Sampling

Prior to Pharmacy Act 90, pharmaceutical companies could provide suppliers of service with 'free' samples that were distributed as trial packs to patients. Sampling itself is a common marketing practice that allows products to be made available to a customer base. The SA government's perspective was that this practice was vulnerable to bribery and corruption and was being abused to by suppliers of service and pharmacies to circumvent VAT and taxation. Sampling is not allowed under the new legislation, however, the wording of the new legislation is unclear as to whether sampling is allowed on compassionate grounds.

3.9.2 Generic Substitution

With the goal of affordable health care in mind, the SA government came out in support of generic substitution and actively supported the concept. It has therefore been incorporated into the legislation so that the consumer is given the choice at the level of the pharmacy of a generic substitute, even if a branded product is scripted. A duty is placed on pharmacists who dispense to ask the patient if a generic substitute is preferred.

The difficulty facing the pharmaceutical industry is that branded products incur huge research and development costs that have to be recouped from product sales before the patent expires. These costs do not apply to companies producing generic drugs, who only have to provide the Medicines Control Council with bioavailability studies for generic drugs to be allowed registration. Further, even though most multinational companies have their own generic division in South Africa, stiff competition is faced from 'illegal' parallel imports from developing countries. There is poor regulation and control of what is available in the SA market and this represents a major threat to growth of the industry. The SA government's position with the industry has been that generics drugs are here to stay.

3.10 CONCLUSION

This chapter focused on the impact that legislative changes in the pharmaceutical sector have already had on the industry. There are several unresolved issues. The pharmaceutical industry has been concerned about the implications of the legislation for the market in South Africa and clarity is required on the confusing aspects of the

legislation. Even though an industry task group was formed to address the controversial areas of donations and sampling of pharmaceutical products, there have been no guidelines issued for the provision by pharmaceutical manufacturers of registered medicinal products for compassionate use or for a marketing code. Chapter Four will consider lessons from the international arena.

CHAPTER FOUR: LESSONS FROM INTERNATIONAL EXPERIENCE

4.1 INTRODUCTION

The pharmaceutical industry globally has been in a state of flux with mergers and acquisitions involving some of the largest conglomerates internationally. The leading pharmaceutical company in the world Pfizer Laboratories recently acquired two major pharmaceutical companies to become the world leader. Simultaneously, there has been a flurry of activity from activists who maintain that giant pharmaceutical companies are solely driven by profit margins, with little social responsibility, hence the high cost of health care. Large conglomerates do invest billions of dollars in research and development, however, there are questions being raised about whether the pharmaceutical industry is in fact driving the swing to evidence-based medicine, so that its products can be utilised by increasing numbers of the population. Lipitor, the drug with the highest sales internationally, marketed by Pfizer Laboratories is an anti-cholesterol drug and many question whether its prescription is necessary in such large numbers. Antidepressants, like Glaxo's Paxil and Lundbeck's Cipralex are listed in the top 10 of drugs sold in the US. There is concern expressed about the cost of these medications, which are justified by the drug companies, as being due to R & D costs (Internet 7).

Worldwide, there is an increasing focus on endorsing the use of generic medicines as a means of saving costs to the health care system. In the UK, generic medicines account for almost 52% by volume of all prescriptions whereas in South Africa, it is estimated that generic usage is of the order of 20% on the market. The economic importance of increasing use of generic medicines was highlighted in the US when new regulations were proposed to limit the ability of drug companies to prolong patent protection. It has been estimated that this change will create savings of some US$3billion for consumers (Internet 4).

Chile faces similar challenges to South Africa, with very similar stratification between a private sector serving some 20% of the population and an overburdened and under-resourced public sector servicing the remaining 80%. A report on their policy choices concluded that it was not clear that the process of privatization of health care or the

098035

financing of health services, and the complete liberalization of drug prices, are the best ways to achieve equitable and rational coverage in respect of drugs in Chile. The state urgently needed to devise mechanisms to exercise its normative functions in regard to drugs in order to prevent the present freedom from degenerating into anarchy (Internet 8).

Both a WHO review on health reform and drug financing and the Austrian Health Institute review of market controls in Europe point to a "pendulum" effect. As governments act on an unfavourable situation by either tightening state control or relying on market instruments, so the local situation reacts, initiating a swing in the opposite direction. The challenge is therefore to minimize the amplitude of the swings, by finding an adequate but flexible mix of interventions. That different countries may be at different parts of the pendulum's swing might go some way to explain the apparent paradox that while developing countries are generally moving towards market-driven policies, developed nations are increasingly resorting to direct interventions. The policy instruments included in most countries' national drug policy (NDP) seem to vacillate between intervention and what has been termed "monitored freedom". This latter course has not been shown to be particularly effective. There are also potential conflicts with overall trade policies as some may also be in conflict with each another. For example, higher levels of price control may inhibit the development of a generic market (Internet 8).

4.2 THE GENERIC DEBATE

Rising prices of medicines are putting essential medicines and other drugs like antidepressants beyond the reach of many people, even in rich countries. In less-developed countries, millions of individuals do not have access to essential drugs, let alone CNS products and drug development is failing to keep up with the major health needs of these countries. The prices of patented medicines usually far exceed the marginal costs of their production. The industry maintains that high prices and patent protection are necessary to compensate for high development costs of innovative products. There is controversy over these claims, as has already been discussed (Internet 8).

Concerns about the harmful effects of the international system of intellectual property rights that are protective towards large conglomerates have led the World Trade Organization to relax the demands placed on least developed countries, and to advocate differential pricing of essential drugs. How these actions will help countries that lack domestic production capacity is unclear. Better access to essential drugs may be achieved rather through voluntary licensing arrangements between international pharmaceutical companies and manufacturers in developing countries and South Africa is no exception (Internet 8). Generic medication seems to be a rather obvious solution to a pressing problem. The controversy is that governments of developing countries are using parallel imports to service their generic market.

4.2.1 The World Health Organisation

A major challenge facing the governments in Africa, including South Africa, is how to provide affordable health care to the majority of the population that cannot be catered for in the private sector. The South African government has stood its ground against the major players in the pharmaceutical industry with regard to the issue of generic medication and parallel imports as their view has been that this is the only feasible option of meeting the need (Internet 5).

There is rising concern that the WHO has permitted a handful of large pharmaceutical companies to exercise undue influence over its polices and programs, and that in particular, the WHO has been intimidated and deterred from exercising leadership on a wide range of trade related issues, and has shrunk from its traditional role in promoting the use of generic drugs in poor countries (Internet 14).

In the area of AIDS, the WHO has been collaborating with big pharmaceutical companies on an ill-advised public relations effort, called the "Accelerating Access Initiative", which is designed to:

- undermine the legitimacy of national campaigns for compulsory licensing of patents on HIV drugs
- pressure poor countries to adopt overly restrictive intellectual property policies in return for extremely limited and unsustainable donation strategies

- undermine the success of Southern African generics producers, who have been the most effective agents in bringing down the prices of HIV drugs (Internet 14).

The central message of the WTO/WHO appears to endorse a model of restrictions on parallel imports on medicines and negotiated discounted prices by big pharmaceutical companies, as it has failed to come out in support of the broader use of parallel imports of medicines and compulsory licensing as sound policy goals (Internet 8). The WHO has obviously not accepted the objective analysis that one of the factors that drove down the prices of HIV drugs in poor countries was the availability of generic medicines or it would have been more proactive with regard to efficient procurement and competitive tendering from generic suppliers.

The WHO needs to direct the process with regard to:

- WHO trademark provisions, an issue of very large importance in generic drugs
- the costs of patent litigation
- the capacity of poor countries to resolve patent disputes
- the implications for poor countries if they lack the practical ability to reject overly broad or non-novel patent claims;
- the costs of "ever-greening" strategies for patents, involving cases where companies seek endless extensions of market exclusivity by filing new patents on old drugs
- the implications of WTO TRIPS restrictions on the export of medicines produced without permission of a patent owner. Specifically, while the WTO TRIPS gives countries fairly broad authority to issue compulsory licenses or authorize government use of patents, for most cases this is predominantly for domestic use, making it problematic for smaller market countries to benefit from such measures, when economies of scale would make it impractical to produce drugs locally. The WHO needs to spell out in practical terms exactly how a rigid interpretation of restrictions on such exports would affect the health care of the poor in smaller market countries.
- Pro-consumer strategies for implementation of TRIPS, Article 39.3 which honours obligations for protecting pharmaceutical drug registration data

- The public health concerns with respect to TRIPS Article 27.1, which requires that patent rights not discriminate on the basis of the field of technology, and in particular, the concerns that a one size fits all patent system will hamper efforts to protect public health interests.
- The extent to which patent exceptions for research serve the public interest, and the policy instruments needed to address problems of excessive intellectual property claims on research tools.
- The need to develop simplified and easier to administer systems for compulsory licensing of patents and the development of model legislation.
- New models for treatment of health care in trade agreements that focus on funding R&D, rather than on the protection of property rights (Internet 8).

4.3 PRIVATE SECTOR DEVELOPMENT IN LOW INCOME COUNTRIES

In recent years there has been a considerable growth of interest in the activities of providers in the private health sector in low-income countries, and in how policy-makers might best capitalize on the accessibility and popularity of this sector. There have been many references to social marketing, accreditation, franchising and contracting as a way forward to developing this market (Internet 8).

4.3.1 Characteristics of the private health sector in low-income countries

The private health sector may be defined as comprising all providers who exist outside the public sector, whether their aim is philanthropic or commercial. In Africa, they include large and small commercial companies, groups of professionals such as doctors, national and international nongovernmental organizations, and individual providers and shopkeepers. The services they provide include hospitals, nursing and maternity homes, clinics run by doctors, nurses, midwives and paramedical workers, diagnostic facilities, e.g. laboratories and radiology units, and the sale of drugs from pharmacies and unqualified static and itinerant drug sellers, including general stores (Internet 13).

In practice, there is a considerable overlap between the public and private sectors. Staff employed in the public sector in most countries also practice privately, either on their own account or working for owners of private facilities. This may be legal or may not be strictly legal or controlled. Public hospitals often operate their own private

wards and manage the income from them, or allow work for private gain on their premises, as when doctors admit private patients and are paid directly by them. This situation needs monitoring because if public services become heavily dependent on fee income, there may be little to distinguish them from private enterprises that operate in the interest of their owners rather than in that of the general public (Internet 13).

The private sector therefore represents a resource that is available and used even in the poorest countries and among lower income groups. However, the effectiveness of private services is often very low, even though they are popular because they are accessible and cheap because there is often adjustment to the purchasing power of the consumer. The use of the more expensive private services, or treatment for chronic conditions, however, can result in households being unable to afford other vital requirements. Over 10% of the income of the poorest quintile of the population is often spent on medical care. The other concern is that rapidly growing private services compete with the public sector for trained human resources. There are pros and cons to the situation as it weakens the public service but opens up the possibilities of using private sector resources to promote public health objectives (Internet 13).

How can the operation of the private market be improved in developing countries? The current situation is the result of interaction between consumers and providers. Consumers make their decisions on which providers to use on the basis of price, available income, their knowledge of different providers, and their preferences for services with different characteristics, particularly relating to quality. Providers are influenced by what it costs them to provide services, what they can charge, their own knowledge, and the regulatory environment. Efforts to improve the current situation should influence demand or supply directly or should seek to restructure the overall environment (Internet 8).

4.3.2 Influencing Consumers

Consumers in low-income countries face a number of problems in relation to the private sector. They often lack knowledge about appropriate means of treating and preventing illness. This translates into low levels of demand for effective disease

control measures. They are dependent on providers for information and this can make them vulnerable to self-interested behaviour by providers. Consumers are usually unable to assess the technical quality of services, with the result that they place more weight on aspects of perceived quality, such as the interpersonal skills of providers and the comfort of the environment in which treatment occurs, both of which may be unrelated to technical competence. They may, therefore, be more exposed to inadequately qualified practitioners providing care of very poor quality. Consumers with low incomes may choose to use practitioners in the informal sector, such as unqualified providers and drug sellers, rather than higher-quality private providers. However, very little is known about the patterns of health-seeking behaviour in different socioeconomic groups in developing countries or about the extent to which the poor rely more than the better-off on low-quality private providers. Relatively few approaches to supporting consumers in their use of the private sector have been tested (Internet 13).

4.3.3 Social marketing

Social marketing is increasingly being used to tackle lack of consumer information. It uses commercial marketing techniques to stimulate demand for effective public health interventions that are then sold, often through the private sector. Social marketing organizations are often non-profit firms or associations, but the products tend to be distributed through various for-profit outlets and nongovernmental organizations. Social marketing has been applied to such diverse interventions as family planning, the treatment of sexually transmitted infections, the use of insecticide-treated mosquito nets, hand-washing and water purification. Although important increases in coverage have been achieved for a wide range of socially marketed interventions, there remains much debate about whether social marketing strengthens the private sector by creating new demand that spills over into demand for full-priced commodities or whether, instead, it crowds out the private commercial sector. The lack of evidence is exacerbated by the fact that social marketing projects tend to measure their success in terms of sales of their own branded products rather than by the development of the market as a whole (Internet 13).

By providing subsidized commodities, social marketing also helps to increase affordability. The level of subsidy differs enormously between projects and types of

intervention; however, the price of a product often covers its cost, leaving the promotion and distribution costs to be covered by public, usually donor, funds. This form of subsidy is usually untargeted, raising the possibility that a substantial share leaks to people who would otherwise have purchased the product at the full price. Furthermore, other measures are needed to ensure access for very poor people who cannot afford even the subsidized product (Internet 13).

There is limited experience with the branding of services and the use of social marketing to promote them. Increasing demand for commodities is likely to be met with an increase in supply, but qualified staff are in short supply and long periods inevitably elapse while new personnel are trained. This means that an increase in demand is likely to result in higher prices and/or staff being drawn from the public sector. In both cases the overall effect on utilization is diminished. To the extent that the social marketing of services succeeds in reorienting demand towards the suppliers of services of higher quality, the incentives to provide high quality can be expected to be strengthened in the long run. In the meantime, however, there is a risk that the tendency for markets to be segmented along income/quality lines will be reinforced, with the usual consequences for equity (Internet 13).

4.3.4 Use of vouchers

Targeted distribution of vouchers that are exchanged for services or products from a private provider is an alternative to an untargeted subsidy at the point of purchase. Vouchers interfere less with the supply side, since providers continue to sell at the market price. They also allow consumers to exercise choice over where they receive services: the money follows the patients, and providers therefore have to compete for business, making them more sensitive to the preferences of patients. A voucher system nevertheless needs a mechanism for determining who qualifies for subsidy, and vouchers can be traded among individuals, making it more difficult to ensure that subsidies reach the target group. Voucher systems have been used for targeting some lower income groups, but their potential remains underexploited (Internet 14).

4.3.5 Consumer protection

Consumers often lack the institutional structure to seek redress when they have been victims of medical malpractice or negligence. One example of the creation of such a structure was the incorporation of private medical practice into the Indian Consumer Protection Act of 1986. A number of improvements followed, but other complementary measures are needed in order to confront the poor quality of care in the private sector (Internet 13).

There are other potential approaches to strengthening the position of consumers in private medical markets. Direct consumer education could help to inform patients about what constitutes care of good quality for a range of common medical procedures; information about prices could help patients when they choose providers; and social marketing approaches could prove useful in publicizing such information. Although regulation and accreditation are, strictly speaking, provider-side interventions, they play an important role in sending clear and transparent signals to consumers about which providers are registered and meet minimum requirements in terms of structure, equipment and staff (Internet 13).

4.3.6 Influencing private providers

Governments of developing countries could use a range of approaches when working with private providers rather than relying on single strategies.

4.3.6.1 Training

The improvement of knowledge and skills is a necessary starting point. Most private providers receive no guidance from the public sector on diagnosis and treatment. Consequently, their practices are determined more by biased information from pharmaceutical companies. Although imaginative ways of disseminating evidence-based information to private providers are insufficient on their own to change behaviour, they offer a potentially affordable strategy that has been little explored. Training is central to most approaches. However, improvements attributable to one-off training may be short-lived, and follow-up and supervision in the private sector is difficult for an under-resourced public sector unable to supervise its own health workers (Internet 13).

4.3.6.2 Regulatory and participative approaches

The private ambulatory sector can be highly competitive, so that success in meeting users' perceived needs and retaining clientele is vital to the economic survival of providers. Private providers may use treatments they know to be ineffective because of actual or perceived user demand. The involvement of service users in the training of providers has successfully reinforced improvements in practice. However, private providers may engage in what they know to be unethical practices in order to maximize income. Regulatory approaches, including consumer protection legislation, have helped to highlight these practices but have done little to control them. An approach that could have great impact in the longer term is for the public sector to work with providers' representative organizations in order to promote professional ethics, building on non-financial incentives such as the desire of providers for social recognition and prestige. Such organizations could also be used to support measures promoting rational drug prescribing, which have mainly been applied in the public sector (Internet 13).

4.3.6.3 Resourcing providers

Private providers may lack access to essential diagnostic services and treatments. One approach has been to provide them with prepackaged drugs for common conditions. However, perverse outcomes can occur, so such strategies require a high level of monitoring.

4.3.6.4 Comprehensive approaches

Some successful projects have adopted a comprehensive approach, improving providers' knowledge and skills, assisting users to recognize and demand good care, and helping providers to apply what they have learnt. In these projects the quality of clinical care was monitored by external assessment, and the project brands were promoted among potential service users: functions that weak public sectors would find difficult to replicate on a national scale. This approach runs the risk of further segmenting the market along income/quality lines though.

4.3.7 Restructuring the market

Recognizing the importance of the private sector in health system outcomes does not imply that the public sector has a diminished role to play. Rather, attention is drawn to the often neglected governmental role of stewardship, without which the private sector operates unchecked and unguided. Governments should regulate the private sector not just in the sense of legislating and administering formal rules but also by intervening to alter the incentives available to private sector institutions and thereby their activities and performance outcomes.

4.3.8 Government stewardship

The concept of stewardship relates not only to the role of government vis-à-vis the private sector but also to a realignment of governmental functions in the public system, which is often both inadequately regulated and inadequately steered towards serving a public health interest. By focusing on the purchasing rather than the providing side of the health services market, government may seek to achieve similar ends in the public sector to those pursued through contracting out policy in the private sector. Formal regulation can influence the number of providers through licensing, but the development of purchasing may create a significant new market to which private providers respond. The separation of purchasers and providers involves the creation of public provider institutions with increased autonomy. These can be expected to compete more vigorously with private sector alternatives (Internet 13).

4.3.9 Contracting out services

Over the past decade, many countries have moved towards greater contracting out to private providers, largely for non- clinical services but also for clinical services, much of the latter having been reported in the unpublished literature. Formal contracts are more common for services that are relatively easy to specify and monitor, e.g. hospital catering and the provision of commodities, whereas less formal, more trust-based relationships are commoner for services that are less easy to specify, e.g. most clinical services. Long-term relationships have traditionally dominated in primary care. This suggests that the development of competition may not be a common outcome of increasing reliance on contractual relationships for clinical services, whether or not the market would otherwise be contestable, or potentially competitive. Indeed, very

little is yet known of the nature of the relationship between purchaser and provider and how this affects the care provided (Internet 13).

4.3.10 Regulating the market

Regulation that primarily aims to intervene strategically in the health service market appears to be relatively rare. In any case, the major issue in regulation is implementation, which has typically been extremely weak, especially in sub-Saharan Africa. This implies that regulation is unlikely to have had a major impact on private providers or on market structure and explains the widespread development of the informal private sector. Growth of the private sector is largely determined externally, even when enabling measures intended to support the sector are in place. Experience gained in a middle- income country suggests that important opportunities to regulate, before the private sector becomes both politically and economically strong enough to resist, should not be missed by low-income countries. Regulation seems to be a function of the market as well as, potentially, an influence on it (Internet 13).

4.3.11 Comprehensive restructuring

Comprehensive attempts to fully restructure the health service market are relatively rare, especially in the very poorest countries. In Zambia the Central Board of Health has been created to perform the purchasing role at national level. It contracts with district health authorities and referral hospitals, both public and nongovernmental. The volume of contractual business with hospitals run by nongovernmental organizations represents a significant departure from a standard integrated public sector approach and alters the demand side of the market considerably. It also offers the opportunity for public coordination of non-profit providers, whereby, for example, the geographical equity of service provision can be increased and the planning of coverage of preventive interventions can be improved. Other effects of reform are constrained by the under-exploitation of the new structures. For example, contract mechanisms permit the relationships between purchasers and providers to mimic those of integrated systems, and health ministry officials continue to intervene directly in the affairs of provider institutions instead of focusing on regulatory and other functions of stewardship. The restructuring approach has yet to be fully tested in a low-income context (Internet 13).

4.3.12 Conclusions regarding developing countries

A fair amount of experience has been gained with private providers in low-income countries. This has not been translated into information about influencing consumer behaviour and restructuring the market. Although some successful efforts to influence private providers have been identified, they are problems. Should South Africa seek to implement some of these measures, it may imply that government is sanctioning treatment practices that are contrary to current policy and there may be strong opposition from powerful professional groups. The monitoring function although vital, would be difficult to sustain in the long term. Consequently, careful judgement has to be made concerning the relative return on investment in improving private sector activities as opposed to investment in a strengthened public sector.

Working with the more organized formal private sector, i.e. doctors, nurses and pharmacists, is a more feasible starting point for the South African government. Training and investment in a stronger formal sector, both private and public, and restructuring the market so as to strengthen the purchasing and regulation functions of government, can go a long way to addressing imbalances, but this is likely to be a very long-term process.

4.4 THE US MARKET

The message that many people are suffering with anxiety and depression and in need of medication has found the spotlight in the US after 9/11. Advertisements for a depression and anxiety campaign have been widespread in TV Guides, Reader's Digest, Time and House and Garden magazines. Pfizer, the world's largest drug maker, spent $5.6 million on TV and magazine ads in October to tell consumers about the benefits of Zoloft for post-traumatic stress disorder (Internet 7).

US statistics for the year 2001 for marketing activities for the following branded antidepressants are included in Table 4.1:

TABLE 4.1 BRANDED ANTIDEPRESSANTS: 2001 STATISTICS

Brand	(Company)	Total
Zoloft	(Pfizer)	45,993,698
Sarafem	(EliLilly)	42,467,315
Paxil	(GlaxoSmithKline)	32,363,685
Ambien	(Pharmacia)	31,666,217
Prozac*	(EliLilly)	31,554,601
Celexa	(ForestLaboratories)	413,450
(AmericanHomeProducts)		5,160
Total for Jan. to Oct. 2001. ...		$184,464,126

Source: Internet 12

Concerns have been raised that the diagnosis of psychiatric conditions and medication prescription is being driven by the drug companies. These concerns have been raised at the APA's annual congress where the sentiment was expressed that a lot of what is considered evidence-based medicine represents a collation of data from industry-sponsored conferences where 'research data' is presented to influence prescription habits of psychiatrists. On closer examination, most of the research is sponsored by drug company grants and represents mere meta-analysis of statistical data from various studies (Internet 7).

This has also raised ethical issues about whether the pharmaceutical industry should have any role to play in the continuing medical education programs of medical doctors. It is felt that the education of physicians is too important to be left to the pharmaceutical industry and is a cause of great concern to the American Psychiatric Association that has been faced with the challenge of finding the right balance with regard to the ethical involvement of the pharmaceutical industry in medical education. There is a growing disquiet about the level of influence that the industry has on the prescription habits of psychiatrists especially in the anti-depressant market, as new uses are found for older products that are nearing the end of their patent in the US (Internet 12).

There are several consumer-based organizations that are fighting back. A new organization, No Free Lunch has been set up to counter pharmaceutical company marketing. It has developed a variety of resources, including a "pen amnesty programme" in which practitioners are invited to send drug company pens to the organization, which will replace them with their own "No Free Lunch" pens. Drug company pens are then donated to charity (Internet 14).

The website home page features a questionnaire to ascertain "drug company dependence". It asks: "Have you ever prescribed Celebrex? Do you get annoyed by people who complain about drug lunches and free gifts? Is there a medication logo on the pen you're using right now? Do you drink your morning eye-opener out of a Lipitor coffee mug? If you answered yes to two or more of the above, you may be drug- company dependent" (Internet 14).

It has initiated a "drug-free practitioners" listing, which is made up of health care providers who have pledged to be "drug company free". The listing aims to provide a mechanism for patients to find health care providers who are ethically practicing medicine, and to raise awareness of this issue both among the public and the medical profession (Internet 14).

4.5 THE UK MARKET

The recent publicity involving the creation of the "super-pharmaceutical" company, with the recent spate of mergers and acquisitions has left feelings of concern within the UK and Europe, about drug companies monopolizing the market. It has highlighted the need for health care professionals to be equipped with skills to appraise pharmaceutical industry marketing materials critically. According to the National Prescribing Centre, in the United Kingdom, the pharmaceutical industry spends about 1.5 per cent of its revenue from sales to the National Health Service on information and 9 per cent on promotion. It can sometimes be difficult to differentiate between industry-sponsored information as a form of education and industry-sponsored information as a form of promotion. Such information is not always accurate and should not be seen as a reliable source of medicines information (Internet 7).

Pharmaceutical marketing has become more sophisticated in recent years. The industry has generally moved on from using advertisements showing dodgy graphs with split axes. However, although direct promotional material must comply with the terms of a product's marketing authorization, evidence to support claims made in advertisements is not always robust. A number still refer to "data on file". When they do refer to published papers these often turn out to be short abstracts for posters presented at an industry-sponsored conference and consequently are unlikely to have been subjected to rigorous peer-review (Internet 7).

Much pharmaceutical advertising relies on highlighting a drug's effects on surrogate markers like lowering cholesterol levels. This is particularly true for antidepressants, the marketing of which frequently relies on empirical evidence (Internet 8) .

4.5.1 Selectively reported results

When trial evidence is available results are often reported selectively to exaggerate the effects of the product. The most commonly used method is to report results as relative risk reduction (RRR), where the percentage reduction in events in the treated group event rate is compared with the control group event rate. Reporting RRR appears to inflate small differences in effect. A more meaningful measure, preferred by proponents of evidence-based medicine (EBM), is absolute risk reduction (ARR), where there is an arithmetic difference in absolute risk between study and control groups. The reciprocal of ARR is the number-needed-to-treat (NNT), which is useful for translating trial results into meaningful figures. Pharmaceutical industry promotional material rarely refers to either ARRs or NNTs (Internet 7).

The National Institute for Clinical Excellence (NICE) guidance in the UK has attempted to counteract some of the marketing strategies of the industry, especially in the case of the marketing of the COX-2 selective inhibitors which are aggressively marketed by Pfizer Laboratories as a breakthrough in anti-inflammatory drugs, however, studies indicate that non-steroidal anti-inflammatory drugs (NSAID's) are still regarded as first-line therapy in a number of situations. NICE guidance has been either used selectively or ignored in the marketing situation (Internet 7).

Companies still market their drugs directly to the consumer in ways that contradict NICE guidance, and there is little that can be done as advertising in the UK only has to comply with the terms of the product's marketing authorization. In addition to direct advertising, a lot of pharmaceutical marketing now employs "infomercial"-type promotion. Some infomercials are quite blatantly promotional; others are subtler and use an "expert" to review information about a product or therapeutic area. Such reviews are supported by educational grants from the pharmaceutical industry and invariably include a statement which says that the views expressed in the publication are those of the author and not necessarily those of the publisher or the pharmaceutical company. They are often provided free of charge either as articles in "free" journals, or as special supplements. Such journals are paid for by advertising (Internet 7).

4.5.2 The Backlash in the UK and Europe

There is a concerted effort being made by concerned parties within the industry to counter the marketing strategies employed by the pharmaceutical industry. A multi-faceted approach is being implemented. Undergraduate and postgraduate training programs are now incorporating the skills needed to appraise pharmaceutical advertising critically. Primary care trusts and other NHS organizations are setting up robust and enforceable policies for managing the entry of new drugs and for dealing with NICE guidance (Internet 7).

This has led to the development of interface formularies, which are formularies across primary and secondary care and more widespread use of clinical decision-making support tools, for objective diagnosis. Organizations have been asked to develop guidelines and policies for working with the pharmaceutical industry, including the setting up registers of interests, in academia (Internet 7).

4.6 A MARKETING CODE FOR THE US

In April 2002, the Pharmaceutical Manufacturer's Executive Committee (PhrMA) which represents the country's leading research-based pharmaceutical and biotechnology companies, adopted a new Marketing Code that governed interactions with healthcare professionals. The voluntary code outlines guidelines for how sales

representatives and others involved in marketing pharmaceuticals should interact with healthcare professionals (Internet 4).

The main points of the new code are as follows:

- **General Interaction**: Interaction should focus on informing the healthcare professional about scientific and educational information and supporting scientific medical research and education to maximize patient benefits.
- **Entertainment**: Interaction should not include entertainment. Interaction should occur at a venue conducive to providing scientific or educational information. Specifically, this means no "dine and dash", no entertainment, and no recreational events, like sporting events or spa visits.
- **Continuing Education**: Companies can provide support to the conference sponsor but should not fund individual participants. That means, a company should not pay an individual's tuition, but could provide support to the event sponsor. That sponsor may in turn provide grants to individuals to participate, or to reduce the overall registration fees for all attendees.
- **Consultants**: Legitimate consulting or advisory arrangements are appropriate but token consulting arrangements should not be used to justify payments to healthcare professionals. Characteristics of legitimate consulting arrangements include the retention of professionals based on their expertise, not as a reward or inducement for prescribing, and retaining no more consultants than needed for the specific program. It would be inappropriate to retain 10,000 physicians for a program that requires no more than 1,000, or to select them as a reward for high prescribing.
- **Educational and Healthcare Practice-related Items**: Educational and practice-related items may be provided to healthcare professionals, but should be for the healthcare benefit of patients and of less than substantial value (100 dollars or less). Items for the personal benefit of the healthcare professional should not be offered or distributed. In short, nothing should be offered or provided that would interfere with the independence of the healthcare professional's prescribing practices (Internet 4).

The PhRMA Code on Interactions with Healthcare Professionals permits informational presentations and discussions that provide valuable scientific and educational benefits by industry representatives and others, speaking on behalf of a

company. The code says, "In connection with such presentations and discussions, meals, but no entertainment or recreational events may be offered so long as they:

(a) are modest as judged by local standards;

(b) occur in a venue and manner conducive to informational communication and provide scientific or educational value" (Internet 7)

Inclusion of a healthcare professional's spouse or other guests is not appropriate. And offering "take-out" meals or meals to be eaten in the absence of a company representative is inappropriate. The code provides that token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. In addition, the code specifies that items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value, however, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not (Internet 7).

The new code also provides that no grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices. The code also contains 10 frequently asked questions and answers to those questions. One question, for example, is whether golf balls and sports bags may be provided if they bear a company or product name (Internet 4).

4.7 IS A MARKETING CODE NECESSARY?

There has been much discussion in the US in response to the PhRMA's decision to develop the new marketing code about whether such a code is necessary and whether there is sufficient infrastructure to implement the monitoring of pharmaceutical companies' relationships with service providers. The medical profession is plagued by perverse incentives from all spheres and this quarter is no different. Advocates of the marketing code point out that some form of regulation is necessary as the situation is

conducive to an unethical, enmeshed relationship between the two industries (Internet 4).

4.7.1 Interactions with representatives

A study by B Hodges (1999) of the University of Toronto into the attitudes of psychiatric residents and clerks to the pharmaceutical industry, using self-report questionnaires, examined the type of interactions with pharmaceutical representatives. 105 residents, interns and clerks training in psychiatry at seven teaching hospitals participated. Less than one third felt that pharmaceutical representatives were a source of accurate information about drugs; however, 71% disagreed with the statement that representatives should be banned from making presentations. Although only 15% felt they had sufficient training about meeting with pharmaceutical representatives, 34% felt that discussions with representatives would have no impact on their prescribing practices, and 56% felt that receiving gifts would have no impact on prescribing. Fewer than half said they would maintain the same degree of contact with representatives if they did not receive promotional gifts. The study found a significant confidence level in the finding that the more money and promotional items a physician-in-training had received, the more likely he or she was to believe that discussions with representatives did not affect prescribing. Supervisors of postgraduate medical training programs were asked to provide instruction concerning potential conflicts of interests inherent in these interactions (Hodges: 2000).

4.7.2 Sampling

Pharmaceutical companies often use drug samples as a marketing strategy in the private sector. There is insufficient information about how the availability of drug samples affects physicians' prescribing practices. A study by Chew and O'Young et al (2000) assessed under what circumstances and why physicians dispensed drug samples, if drug samples lead physicians to use medications other than their preferred drug choice, and the physician characteristics that were associated with drug sample use. 154 general medicine and family physicians were included in the study which involved physicians' self-reported prescribing patterns for 3 clinical scenarios, including their preferred drug choice, whether they would use a drug sample and subsequently prescribe the sampled medication, and the importance of factors involved in the decision to dispense a drug sample. Avoiding cost to the patient was

the most consistent motivator for dispensing a drug sample for all 3 case scenarios that were presented to the doctors. The study concluded that the availability of drug samples led physicians to dispense and subsequently prescribe drugs that differ from their preferred drug choice.

4.7.2.1 Misuse of samples

One of the concerns about the distribution of samples by pharmaceutical companies to suppliers of service is the possibility of bribery and corruption. Tong & Lien (1995) used a voluntary questionnaire survey to determine whether pharmaceutical representatives misused their samples. The study was undertaken over a period of 3 months and 27 representatives were surveyed. 59% had provided prescription drug samples to friends or relatives, the most commonly sampled drug being non-steroidal anti-inflammatory drugs.

4.7.3 Detailing by representatives

Pharmaceutical companies in industrialized countries generally view detailers as the most crucial element in the promotion of their products, with the result that over 50 percent of expenditures on promotion are devoted to detailers. In the United States there is one drug representative for every 15 practising physicians. The standard sales pitch is rife with information on a drug's effect on cellular receptors, its in-vitro inhibitory activity, or its effect on serum concentrations. Companies make claims that the detailers have the scientific knowledge for their role in passing on information to physicians, however, the validity of information presented by drug representatives varies with their level of knowledge and their zeal in conveying their message. A recent analysis of the accuracy of information from representatives found that one in 10 statements, all of which favoured their product, were at odds with the company's own literature. The main purpose of detailers then is to sell their company's products. This emphasis on sales is evident from statements of detailers themselves, from advertisements for detailers, from company documents, and by looking at the groups of physicians that companies specially target for visits by detailers. A variety of explanations are offered as to why physicians see detailers, but on examination none of the reasons is justifiable. Studies from a number of industrialized countries have shown that over 90 percent of physicians see detailers and a substantial percentage rely heavily on detailers as sources of information about therapeutics. Detailers are

highly successful in altering physicians' prescribing habits, but almost all the literature available shows that the more reliant doctors are on commercial sources of information, the less appropriate they are as prescribers (Internet 13).

4.7.3.1 Detail Aids

The detail aids used by pharmaceutical companies to present information to doctors is also the branded material presented to the doctor regarding the company's product. Stryer & Bero (1996) evaluated the characteristics of material distributed by pharmaceutical companies to physicians to determine whether the material complied with Food and Drug Administration (FDA) regulations and whether it contained promotional and educational characteristics. Forty-two percent of the items failed to comply with at least one of three FDA regulations assessed, including 17 items that discussed unapproved uses for drugs. Advertisements, as well as items that were not obviously promotional, contained promotional characteristics. Thirty-nine percent of the items offered scientific support for their claims. The study concluded that little of the material distributed by pharmaceutical companies to physicians conveyed information about important therapeutic breakthroughs and some of it failed to comply with FDA regulations. The material always contained both educational and promotional characteristics.

4.7.4 Prescription Habits

The consistent argument for the regulation of interactions between the pharmaceutical industry and the medical profession is that the relationship would be one of undue influence where the practitioners' prescription habits would be altered. A study by Orlowski and Wateski et al (1992) examined the impact on physician prescribing patterns of pharmaceutical firms offering all-expenses-paid trips to popular sunbelt vacation sites to attend symposia sponsored by a pharmaceutical company. The impact was assessed by tracking the pharmacy inventory usage reports for two drugs before and after the symposia. Both drugs were available only as intravenous preparations and could be used only on hospitalized patients. The usage patterns were tracked for 22 months preceding each symposium and for 17 months after each symposium. Ten physicians invited to each symposium were interviewed about the likelihood that such an enticement would affect their prescribing patterns. A significant increase in the prescribing pattern of both drugs occurred following the

symposia. These changed prescribing patterns were also significantly different from the national usage patterns of the two drugs by hospitals with more than 500 beds and major medical centers over the same period of time. These alterations in prescribing patterns occurred even though the majority of physicians who attended the symposia believed that such enticements would not alter their prescribing patterns.

4.7.5 Journal Advertising

The pharmaceutical industry spends a significant proportion of its marketing budget on advertising in leading medical journals. The larger companies with the bigger budget are able to hog this space and see this as a competitive advantage. A study by Wilkes, Doblin et al (2000) assessed both the accuracy of scientific data presented in print pharmaceutical advertisements and the compliance of these advertisements with Food and Drug Administration (FDA) standards. A cross-sectional survey of 109 full-page pharmaceutical advertisements appearing in 10 leading medical journals, along with all available references cited in the advertisement were sent to three reviewers: two physicians in the relevant clinical area who were experienced in peer review and one academic clinical pharmacist.

Reviewers were asked to evaluate the advertisements using criteria based on FDA guidelines, to judge the educational value and overall quality of the advertisements, and to make a recommendation regarding publication. In 30% of cases, reviewers disagreed with the advertisers' claim that the drug was the "drug of choice." Reviewers felt that information on efficacy was balanced with that on side effects and contraindications in 49% of advertisements but was not balanced in 40%. Reviewers agreed with advertisements' claims that the drug was safe in 86% of the cases but judged that headlines in 32% of the advertisements containing headlines misled the reader about efficacy. In 44% of cases, reviewers felt that the advertisement would lead to improper prescribing if a physician had no other information about the drug other than that contained in the advertisement. Fifty-seven percent of advertisements were judged by two or more reviewers to have little or no educational value. Overall, reviewers would not have recommended publication of 28% of the advertisements and would have required major revisions in 34% before publication.

The study concluded that in the opinion of the reviewers, many advertisements contained deficiencies in areas in which the FDA has established explicit standards of quality. It recommended that new strategies be employed by the pharmaceutical industry to ensure that advertisements comply with standards in order to promote proper use of products so as to protect the consumer.

4.7.6 Promotional Gifts

Another area of investment by pharmaceutical companies is in the distribution of promotional gifts to its customer base. While this is an acceptable marketing practice in other sectors of the economy little is known about the factors that influence medical professional attitudes toward pharmaceutical industry promotions or, how such attitudes correlate with physician behavior. A study by Steinman, Shlipak et al (2001), investigated the attitudes of 105 interns, using confidential surveys. The majority of respondents considered seven of nine types of promotions appropriate. Residents judged the appropriateness of promotions on the basis of their cost. Most respondents stated that industry promotions and contacts did not influence their own prescribing, but only 16% believed other physicians were similarly unaffected. The study concluded that although generally positive attitudes were present toward gifts from the pharmaceutical industry, there is a belief that behavior is not influenced by the companies even though report behaviors in the study were often inconsistent with their attitudes.

4.8 CONCLUSION

The international experience of the relationship between the pharmaceutical industry and the medical profession lends support to the South African government's stance on regulation of the marketing activities of the pharmaceutical industry. In every aspect of contact between the two sectors, there exists the potential for unethical influence on the prescription habits of practitioners for the purpose of sales figures. The final chapter will discuss recommendations for the South African situation, with specific reference to generic substitution, parallel imports, and Section 12 of Pharmacy Act 90 with regard to issues of sampling, removal of incentives and the constitution of a marketing code.

CHAPTER FIVE: RECOMMENDATIONS AND CONCLUSIONS

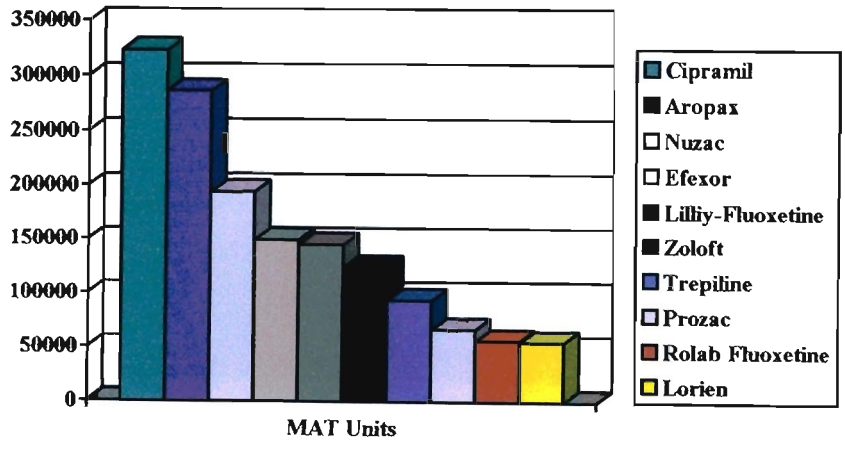
5.1 INTRODUCTION

This case study was undertaken to evaluate the impact of legislative changes on stakeholders in the pharmaceutical industry. In the preceding chapters we have discussed the stakeholders, described the legislative changes and strategically analyzed the industry. Exploration of the international experience of the regulation of the pharmaceutical industry appears to hint at pros and cons to the stance of the South African government. In this chapter, we will comment on the impact of the restrictions with regard to sampling, removal of incentives and generic medication on psychiatric practice. This evaluation makes the assumption that the issues are translatable to the industry at large in South Africa. Further, recommendations regarding the constituents of a marketing code will be highlighted.

5.2 GENERIC SUBSTITUTION

Statistics of the South African anti-depressant market (TPM: Total Private Market) for the year 2001 are reflected in Graphs 5.1 and 5.2 below (Internet 7).

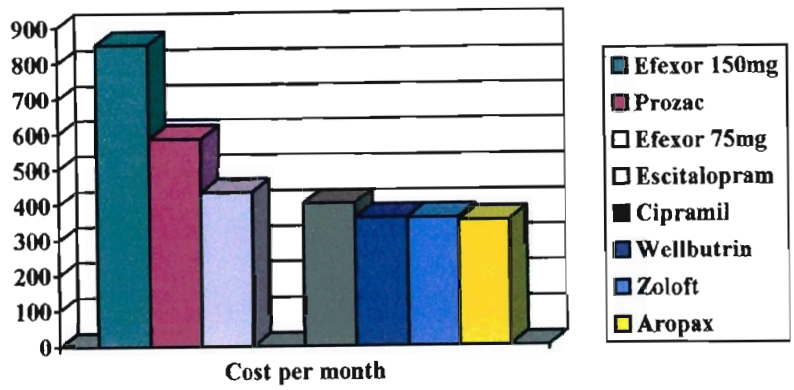
GRAPH 5.I : Antidepressant Units Used in SA in 2001



(Number of units prescribed per month)

Source: Internet 7

GRAPH 5.2: Cost of Antidepressants Used in SA in 2001



Source: Internet 7

These figures of the South African antidepressant market are similar to the statistics of the US and indicate that the trends in the South African market follow those of the US quite closely, even to similarities between the market leaders (Internet 7). There are several reasons why this may be the case:

- Diagnostically, SA psychiatrists use the DSM-IV system of classification of mental illness that is US-based. This is versus the European classification of mental illness that is based on the ICD-10 classification.
- The market leaders in the US have local subsidiaries in South Africa
- There is aggressive marketing of branded products in the South African market
- There is aggressive marketing of branded products in leading publications
- There is investment in R & D in the area of CNS products and there have been new product launches yearly
- The level of contact between the pharmaceutical industry and psychiatrists is high

As is the case in the US, branded products are still the preferred products in private practice, despite legislation to the contrary. There is still suspicion among private practitioners about generic medication. Concerns are raised about the efficacy and tolerability of the substitutes. There is also a lack of experience in the use of generic medication as the private practice market has bee focused mainly on branded products. As a nation South Africans are very brand conscious in general and this

expectation that 'branded is better' also rings true for medication. The health provider is not the only pro party in the equation as the consumer also feels that generic medication is less potent than the 'real stuff'. With regard to efficacy, it is then impossible to determine, either for the practitioner or the consumer, whether the perception that branded products are better, influences response or whether there is a significant difference in efficacy. Certainly at the level of the MCC, there appears to no disbelief in the tolerability of generic drugs, as no other data is required other than bioavailability studies for registration. Branded products are actively being bypassed in the queue so that generic medications can be supported by government agencies.

SASOP'S position is clear. Although there is the reality of problems with affordability, it is a concern that the EDL has been constituted with so few of the branded products that genuinely represent a breakthrough in treatment. The field of psychiatry is rapidly advancing and there are new developments in psychopharmacology. There are also serious concerns about the safety and tolerability of some of the older preparations that have made the EDL. SASOP has indicated that it would not oppose the EDL but it has indicated its reservations regarding some of the treatment options available.

The second area of restriction on the use of branded products comes from the administrators of health care in the private sector, who impose limits on medication use. Certain medical aid schemes like Mx Health have designed their accepted formulary on the EDL and will not pay for certain branded products, even if the patient wishes to use his entire annual limit for that prescription. This can be construed as an infringement on the consumer's right to privacy. Further, there are also restrictions as to what constitutes chronic medication, which is defined as life-saving medication. Here again, administrators have guidelines and limits and patients who belong to the Schemes have little flexibility. The Schemes have now introduced specialist verification of scripts for longer than six months, thereby necessitating a visit to a specialist, which does not help in the reduction of costs.

In the public sector, generic medication is the treatment of choice and branded products are rarely available. Concerns have been raised about the training of health

professionals with limited exposure to a range of medication before they are licenced to practice in the private sector.

5.2.1 The NAPM's Perspective on Generic Medication

The National Association of Pharmaceutical Manufacturers (NAPM) welcomed the implementation of the Medicines Control Amendment Act which came into force at the beginning of May 2003, as it opened up opportunities for investment in the local generics sector.Generic substitution is viewed as a direct benefit to consumers by the NAPM and the Association is in the process of implementing a marketing campaign which will educate consumers and healthcare professionals on the advantages of generic medicines.

In terms of the legislation, introduced in May, it is mandatory for pharmacists or other dispensers to inform patients of the benefits of Interchangeable Multi-Source medicines (IMM). IMM is defined as 'medicines that contain the same substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards which comply with the requirements for therapeutic equivalence as prescribed' (Internet 1).

The NAPM is satisfied that the therapeutic equivalence determined from comparative bioavailability, pharmacodynamic, clinical or in vitro studies, meet the requirements and criteria for bioequivalence as determined by the Medicines Control Council. The legislation states that IMM must be dispensed unless expressly forbidden by the patient and the dispenser must take all reasonable steps to inform the prescriber of such substitution. This has implied that unless the prescriber writes no substitution on the prescription, there is no guarantee that the consumer would receive what was scripted.

There are safeguards that in that generic substitution is not permitted if expressly prohibited by the prescriber, or IMM is more expensive, or the original medicine has been declared 'non-substitutable' by the Medicines Control Council. The NAPM feels that in South Africa, generic medicines currently account for about 20% of the South African market, which indicates that there is considerable room to improve the affordability of medicines through increased use of generics. It is no secret that the

agenda of the organisation is that this represents a massive opportunity for the manufacturers of generic medicines. The NAPM has therefore urged its members not only to promote the use of generic medicines but also to actively seek to work as closely as possible with the Department of Health by proposing affordable solutions for pharmaceutical care that will be in the best interests of the patient (Internet 1).

5.3 THE NATIONAL DRUG POLICY

The South African legislation is aimed at lowering drug prices by allowing importation of generic substitutes and imposition of compulsory licensing. At stake however, are the sovereignty of patent law and World Trade Organization rules on Trade in Intellectual Property and international power relations between developing countries and the pharmaceutical industry. In reviewing the ongoing debate, the situation raises concerns about contemporary imperialism, the role of the profit motive as an incentive in vital pharmaceutical products, and the depth of "democracy" in the US where international drug firms have sufficient clout to dictate policy against the life-and-death interests of millions of consumers of essential drugs in South Africa and other developing countries (Internet 5).

What is clearly needed in South Africa is action on some of the NDP steps that closely match those suggested by the WHO as general advice to all countries:

- More detailed data on price trends in both the private and public sectors
- More analysis of the impacts of policy decisions, with emphasis on indicators of equity, affordability and availability
- Finality on those policy choices which seem to hold clear advantages such as fixed professional fees and non-discriminatory exit pricing based on volume
- Finality on the legal struggle to introduce generic substitution, to regulate marketing practices and to exploit the safeguards provided by the TRIPS Agreement
- Consideration of regional options, including bulk purchasing across the SADC region.

In South Africa, crucial to the success of these options will be strengthening of the national Departments responsible, the Directorate of: Pharmaceutical Programmes and Planning and the Directorate: Medicines Administration, the secretariat to the

Medicines Control Council. Significant strengthening of the inspectorate functions of the MCC will also be necessary if the potential pitfalls of parallel trade and compulsory licensing are to be avoided. Strengthening the entire system will ensure that the populace is not exposed to counterfeit and sub-standard medicines and will demonstrate that such exposure is not an inevitable consequence of the policy choices outlined in this chapter. In this regard, South Africa still remains a test case, one watched closely by the international community (Internet 5).

5.4 A CODE OF CONDUCT FOR THE PHARMACEUTICAL INDUSTRY

It is clear that a framework of good practice to audit companies' behaviour on issues relevant to patient care needs to be formulated. However, there are bigger ethical issues than the industry's relationship with providers of service. The biggest issue is whether the companies are prepared to be socially responsible, by reducing prices systematically for poor countries and directing some of its enormous drug development capabilities to neglected health needs.

Ensuring social responsibility from the industry in the long term depends on socially responsible government policies at the country level. An international convention could be developed to ensure that new medicines are developed according to global health needs, and equitable drug pricing can be ensured through a mandatory framework. However, such policies are unlikely to be forthcoming while the pharmaceutical industry continues to influence governments to the extent it currently does.

5.5 THE PLACE OF PRIVATE PRACTICE IN SOUTH AFRICA

The use of private health care providers in low-and middle-income countries (LMICs) is widespread and its implications are the subject of continuing debate. One view is that private providers are likely to be more efficient than the public sector and hence that government should contract out services to the private sector. An alternative view is that private providers are often not superior in quality or efficiency to the public

sector, and that contracts are not straightforward to design and implement. Finally, there is increasing recognition that neither public nor private providers have uniform characteristics, and that this distinction might overlook more important issues, such as the extent to which a provider uses public funds efficiently and serves the goals of public health (Internet 8).

A new model of private primary care provision could be developed in South Africa, in which private companies provide standardized primary care services at a relatively low cost. Drawing on data from other low-income countries where there is service delivery, this represents the most likely alternative for patients on a low income with no access to health care.

The fact that public sector primary care is free in South Africa, yet around 30% of people without medical insurance still choose to pay out of their own pocket to attend facilities in the private sector, is a telling statistic. Even in the lowest income quintile this proportion is estimated to be 20%. The market for private patients is lucrative and most general practitioners are in private practice. The private sector is a feasible option in urban areas as patients appreciate the service delivery because of perceptions of greater privacy, speed of service, and quality of diagnosis, prescribing and counseling (Internet 2).

Currently, there are more 100 private, branded, primary care clinics in South Africa owned by a handful of companies. Larger companies are achieving widespread coverage and brand recognition. Some company managers have also expressed an interest in contracting with the government to deliver services on their behalf, but as yet they have had no clear response from the South African Department of Health. Patterns of use differed markedly at the private clinics compared with the public sector. Patients appeared to "shop around" between different providers for different services, tending to use the public sector for treatment of chronic conditions and private clinics for curative care.

What are the implications of this new model of primary care for the current debate about the role of the private sector in public–private partnerships, and how will the public health care system react to the possibility? For the public sector, in its current

mode of operation, this model of private provider presents threats and opportunities. One direct threat is competition for primary health care nurses who are in short supply and who traditionally have been employed largely by the public sector.
Other possibilities posed by this new model relate to its probable impact on the shape of the health care system. The low-income segment of the population could be serviced by the private sector, while the public sector concentrates on its role as regulator and providing services to the poorest. Potentially, this could remove some of the burden on the public sector, and the task of regulation might be made easier by the strong hierarchical control exercised within the private sector. One drawback is the desirability of encouraging any low-income group to pay for primary care services is also debatable.

An alternative form of cooperation would be for the government to contract with these companies to provide services to the whole population. Clinic chains can deliver services that are very acceptable to users and which are at a similar cost to the public sector, and they are attracted by the market expansion that contracting with government would offer. In addition, contracts with a hierarchically structured company might be easier to manage than with a series of self- employed professionals such as general practitioners, because the internal management systems and standardized procedures of the former would lessen the variation in service delivery and give greater control. In addition, contracts could secure access for the poorest section of the population and draw the clinics into the framework of public sector service delivery, offering a similar range of services, rather than allowing them to remain largely as complements to the public sector.

However, many real-life constraints, of market structure, information and capacity, would need to be taken into account in designing and implementing such a system. The South African experience of contracts for district hospital provision and curative primary care services emphasizes the crucial prerequisite of adequate public sector capacity to manage these constraints effectively, especially when dealing with agile and creative private companies, although positive experiences of contracting out have been recorded in a variety of settings. Scepticism among some policy makers and managers about the desirability of working with the private sector, and of their motivations, is a further potential hurdle (Internet 5).

5.6 PARALLEL IMPORTS

Several large pharmaceutical companies have asked US trade officials to put pressure on the South Africa government to modify the country's policies with regard to the regulation of pharmaceutical drugs. The South African government, however, is working closely with the World Health Organization (WHO) to adopt policies which may serve as a model for other developing countries in Africa and elsewhere. One of the issues in dispute concerns the matter of parallel imports for pharmaceutical drugs. The South African government has lowered regulatory barriers for the importation of registered pharmaceutical drugs as it believes its consumers will benefit if hospitals and other health care providers can seek the procurement of pharmaceutical drugs in the broader world market. Parallel imports are legal within the European Community and account for 8 percent of the UK pharmaceutical drug market, and 5 to 10 percent of the Netherlands market. The SA government is committed to its stance and is swinging world support its way.

5.7 CLARITY OF LEGISLATION

Section 18B (1) of the Medicines and Related Substances Control Amendment Act No. 90 of 1997 prohibits the sampling of any medicine by any person. However Section 18 (2) clarifies this by defining what is meant by "sample" i.e. The free supply of medicines BY a manufacturer or wholesaler, or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act 1974. It goes on to clarify that this ban does NOT include the free supply of medicines for:

a) the purposes of clinical trials
b) donations of medicines to the State and
c) quality control by inspectors.

Presumably the supply of a sample of a medicine to the Medicines Control Council for registration purposes would fall under c) above (Internet 5).

It has been the practice in South Africa for many years for companies to donate medicines to the many private charities which offer medical and clinical services to

the indigent and unemployed in areas where the there are no State services or where these are inadequate to meet the needs of the public. This is also the case in certain private hospitals run by various religious orders or missionaries in which doctors and nurses offer a wide range of medical care. There are also many clinics run by NGO's which are staffed by part-time medical practitioners, nurses and other health care practitioners who have benefited from "donations" or "samples" supplied by pharmaceutical companies as part of their social responsibility programmes eg. Alexandra Clinic.

An alternative designation could be that the products are donated or made available for "compassionate" reasons given the urgent need for such programmes in this country. Such products are not donated or given away as samples for promotional purposes since the limited budgets of the various clinics and hospitals would not allow for the purchase of these products. Stocks are properly controlled and used under the supervision of registered heath care professionals.

Donations such as these described above are now illegal according to Section 18B of Act 101 of 1965 as amended, since they do not fit into any of the categories for exemption described in the Act. The medicines are supplied free of charge but they are not promotional samples. However, they are also not one of the sample categories that are permitted. The medicines donated are not for use by the State; they are not samples for tender, quality control, analytical purposes or to go to the MCC with applications for registration of new medicines.

Through the Industry Task Group [ITG], the South African pharmaceutical industry should propose to government that a special category of "compassionate use" donations of REGISTERED medicines, should be permitted for distribution to designated charities running clinics, hospitals, or providing medical services for the indigent, and unemployed in areas where there are inadequate or no State services, or where the State services cannot not offer the treatment needed, as in the case of the daily medicine needs for a home for abandoned or orphaned babies with HIV /AIDS. The current provision of "compassionate use" samples generally relates to new unregistered medicines for patients who do not respond to the standard treatment available or for whom such treatment is not suitable.

At the moment,

a) Section 21 does not cover the supply of registered medicines for compassionate use;
b) the current prohibition on the sampling of medicines is contained in Section 18B of Act 101 of 1965 as amended, and that a change in this Section of the Act would require returning to Parliament for an amendment to the legislation.
c) However it is not clear if a "no charge" supply of medicines for compassionate purposes would be regarded as "samples" or "a donation" as listed in the Act and if a change in the legislation is in fact required at all.

Should a change in legislation be required, an additional statement in clause 18B(2) could read:

"18B(2): For the purposes of this section "sample" means the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, but does not include the free of supply of medicines for

a) the purposes of clinical trials,
b) donations of medicines to the State,
c) <u>donations to a registered charity or NGO approved by the Minister or a designated State official</u>,
d) tendering to the State and
e) quality control by inspectors."

In addition, Guidelines outlining conditions for the free supply of medicines for Compassionate Use for individuals or for patients at designated private clinics or hospitals could be issued. The current provision of "compassionate use" medicines under Section 21 of Act 101 of 1965, generally relates to new unregistered medicines for patients who do not respond to the standard treatment available or for whom such treatment is not suitable.

This guideline covers the supply of registered medicines by manufacturers, or wholesalers, free of charge to non-governmental organizations or individuals for compassionate use. This would include registered charities, which run clinics, or

hospitals, and NGO's which assist the indigent and unemployed who might not be able to afford medical treatment, in areas where there are inadequate or no State services, or where the State services cannot offer the treatment needed. Donations of medicines for such people should be made directly to a health care professional registered with one of the relevant Statutory Health Councils and the control and issuing of such donated medicines should be done by personnel with the appropriate qualifications and authority. All required records must be kept by the responsible health care professional.

Applications for approval of any donation of a registered medicine to other than registered charities, could be made to the Minister or a designated official of the Department of Health [or the MCC].

5.8 A MARKETING CODE

Sales and marketing compliance is clearly becoming a major industry issue as companies strive to undertake internal reviews to ensure compliance with "anti-kickback" laws and avoid unwelcome publicity. However, as marketing potential reaches saturation, the industry needs to extend its promotional influence while remaining within the confines of regulatory law.

Clearly, the industry is under pressure to review sales and marketing practices as increasing flaws are found in the influencing strategies that pharmaceutical companies currently apply to prescribers. The World Medical Association is also reviewing the relationship between the medical community and pharmaceutical marketers to determine the extent of alleged influence. Practices such as product sampling, educational sessions aimed at physicians and sponsored research are under review.

In an attempt to boost prescription volumes, companies are under pressure to match the promotional spend of competitors to maintain their sales force share of voice. Detailing is still viewed as the key way to reach doctors and companies have increased the size of their sales force by about 75% over the past six years (Internet 7).

The principles behind a Marketing Code should be based on legislation relating to medicinal products, consumers and competition and on the International Code of Advertising Practice. The Code of Conduct should cover marketing activities in medical journals, promotional and educational materials used by medical representatives, trade displays, medical education, and supply of information to the general public and healthcare professionals.

An independent Code of Conduct Committee, made up of representatives from the medical profession, government, industry, and consumer groups could investigate complaints about breaches of the Code and impose sanctions such as fines or publication of corrective advertising.

The purpose of this code would be to ensure that the marketing of medicines by all pharmaceutical companies to health professionals and the general public in South Africa is carried out in a responsible and ethical manner. All pharmaceutical companies supplying drugs in South Africa will be subject to this code by virtue of registering their products with the Medicines Control Council. Punitive measures will be applied against a company ruled in breach of the code.

The code could be divided into three parts: Part I dealing with the promotion of medicines to health professionals, Part 11 dealing with the promotion of over-the-counter medicines to the general public and Part III relating to the Authority that will monitor the Code and administer the complaints procedure.

All pharmaceutical companies would be expected to assume responsibility to know the parameters of the code and to ensure that appropriate personnel within their companies and their advertising agencies have a comprehensive understanding of the code. The Code could include the following constituents:

- Media advertising, detail aids and other promotional material should include a considerable amount of prescribing information and may only appear in professional publications.
- Each company should have a standard operating procedure for the certification process for promotional material which must be available for audit by the MCC or the Authority. Promotional material may be issued only its final form

without any subsequent amendments after it has been certified by two persons on behalf of the company. One of the two persons should be a registered medical practitioner or a responsible. The other signatory could be an appropriate senior official of the company.

- Certification should be maintained also for promotional material and meetings being organized for health professionals that involve travel outside South Africa. Certificates and the relevant accompanying information must be preserved for not less than three years.
- Medical representatives should have a minimum standard of training that could be decided on by the industry.
- No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage should be offered or given to health professionals or administrative staff or government officials or to the general public as an inducement to prescribe, supply, stock, dispense, administer or buy any medicines.
- The only exceptions to the code are inexpensive gifts in the form of promotional aids or prizes. Competitions are permissible but must be in good taste and appropriate for the promotion of medicine.
- Hospitality may include the payment of reasonable, actual travel costs for delegates to attend meetings in South Africa but such payments should only be made to the professional associations organizing the event.
- Sponsorship of meetings could be permitted but the meeting must have a clear educational content and the hospitality associated with the meeting must be secondary and not out of proportion. Hospitality should not be extended to spouses or other persons unless that person is a member of the health professions or qualifies as a delegate in his/her own right. Meetings for groups of health professionals or administrative staff that are wholly or mainly of a sporting or social nature should not be acceptable.

5.9. CONCLUSIONS

This case study attempted to evaluate the impact of the legislative changes on all stakeholders in the pharmaceutical industry. Gap analysis revealed that all stakeholders had perceived a real difference between the industry five years ago and now. With the legislative changes being so fundamentally different from the old legislation with regard to significant areas of the industry it is clear, that the impact of the legislation would cause a further gap between where the stakeholders perceive the industry is at present and where they would like it to be.

The SA government would like to be in a position of offering affordable health care to its people and the region and continent and would like to be seen as a regional leader in the fight to have the costs of medication reduced. The legislation has begun a process whereby that could be a reality in the next decade. For the pharmaceutical industry, which has been a global leader as an industry, this Act represents a major challenge to retaining its profit margins in a global economy that is in recession. What is required of the industry is to become innovative in its strategy, to be collaborative in its approach with government and to pursue horizontal and vertical integration actively. Social responsibility and establishing sustainable competitive advantage would be invaluable to the major role players in the industry, as the demand from governments increase for reduction in drug costs. The justification of high R & D costs is falling on deaf ears and the industry has to move quickly to address the negative drift it is experiencing even in the developed world. For the providers of service, the Act represents a difficulty in providing adequate care to a section of the population that needs it the most. Sampling was a valuable way of allowing low income groups to have access to branded products. With regard to incentives, especially in this country with its history of imbalance, there is some support among professionals for the equitable distribution of sponsorship for educational events. The issue of generic substitution and managed health care is more relevant as a factor that could impact significantly on private practice in South Africa.

Presently, it is clear that the changes with regard to promotion of generic substitutes, removal of samples and the banning of perverse incentives would impact largely on the private sector. It is also clear that the changes in legislation were a necessary 'evil'

if South Africa was going to meet its commitments to provide affordable health care to its citizens. Its policy on generic substitution and parallel imports has been supported within the country and outside, in the developing world and Europe.

The development of a code of conduct that would regulate the relationship between the industry and health providers is long overdue and in keeping with international trends. However, clarification regarding legislation with regard to sampling is a factor that needs urgent attention. There is a percentage of consumers in both the private and public sector that were benefiting from this practice, that have been marginalized. The government also needs to consider private-public sector partnerships as a way forward in addressing its objectives in providing effective, affordable health care.

REFERENCES

Babbie, E. 1998. The Practice of Social Research. 8th ed. Belmont: Wadsworth.

Benbasat, I. 1984. An Analysis of Research Methodologies. *Harvard School Press*: 47-87.

Chetty, S. 1996. The Case Study Method For Research In Small-And Medium-Sized Firms. *International Small Business Journal* ; **(1)**: 73-88.

Chew LD, O'Young et al., 2000.A physican's survey of the drug sample availability on behavior. *J Gen Intern Med* ; **(7)** : 478-483.

Cooper, C.R. and Schindler, P.S. 2001. *Business Research Methods.* 7th ed. Boston: McGraw-Hill.

D'Aveni, Richard A. 1994.*Hypercompetition: Managing the Dynamics of Srategic Maneuvering.* New York: The Free Press.

Devers, K.J.1999. How Will We Know " Good Qualitative Research When We See It? Beginning The Dialogue In Health Services Research [online]. Available from http://www.findarticles.com/cf_0/m4149/5_34/58451870/pron.jhtm. [Accessed: 20/04/2003].

Ghauri, P.,Gronhaug, K. and Kristianslund, I. 1995. *Research Methods in Business Studies: A Practical Guide*. London: Prentice Hall.

Hamel, Gary.2000. *Leading the Revolution.* Boston: Harvard Business School Press.

Hill, C.W.L.2002.*International Business: Competing in the Global Marketplace: Postscript 2002*. 3rd ed. Boston: McGraw-Hill.

Hodges B, 2000. Interactions with the pharmaceutical industry: experiences and attitudes of psychiatry residents, interns and clerks ; *Can Am J.* **(8)** : 450-456.

Internet 1: http://www.napm.co.za

Internet 2: http://www.sasop.co.za

Internet 3: http://www.sama.co.za

Internet 4: http://www.marketresearch.com

Internet 5: http://www.doh.gov.za

Internet 6: http://www.hpcsa.co.za

Internet 7: http://www.marketfacts.com

Internet 8: http://www.hst.org.za/sahr/2000

Internet 9: http://www.dis.unimelb.edu.au

Internet 10: http://www.managerialdesign.com./planning

Internet 11: http://www.quickmba.com

Internet 12: http://www.tutor2u.net/business/strategy

Internet 13: http://www.who.org

Internet 14: http://www.nofreelunch.org

Internet 15:http://www.marketingteacher.com

Internet 16: http://www.lilly.co.za

Internet 17: http://www.pfizer.com

Johnson, G and Scholes, K. 1999. *Exploring Corporate Strategy.* 5th ed. London: Prentice Hall.

Kotler, P.1997. *Marketing Management: Analysis, Planning, Implementation and Control.* 9th ed. New Jersey: Prentice Hall.

Leedy, P.D. and Ormond, J.E.2001. *Practical Research: Planning and Design.* 7th ed. New Jersey: Prentice Hall.

Lex Chin, J., 1989. Doctors and detailers: therapeutic education or pharmaceutical promotion. *Int J Health Services* ; **(4)** : 663-670.

Lynch, R. 2000. *Corporate Strategy.* 2nd ed. Harlow: Prentice Hall.

Markides,C.C. 2000. *All the Right Moves: A Guide to Crafting Breakthrough Strategy.* Boston, MA: Harvard Business School Press.

Orlowski JP, Wateski L, et al., 1992. The effects of pharmaceutical firms incentives on physician prescribing patterns. There's no such thing as a free lunch. *Chest* ; **(1)** : 270-273.

Patton, M.Q. 1999. Enhancing the Quality and Credibility of Qualitative Analysis [online].Available http://www.findarticles.co./cf_0/m4149/5_34/5851871/print.jhtm [Accessed 20/04/03]

Pearce, J.A. and Robinson, R.B. 1997. *Strategic Management: Formulation, Implementation and Control.* 6th ed. Chicago: Irwin.

Porter, M.E. 1998. *Competitive Advantage: Creating and Sustaining Superior Performance.* New York: Free Press.

Porter, M.E. 1998. *Competitive Strategy Techniques for Analyzing Industries and Competitors.* New York: Free Press.

Prahalad, CK and Hamel G. 1990. "The Core Competence of the Corporation". *Harvard Business Review, May-June,* pp. 79-91.

Reclies,D. 2001. Porter's Diamond – Determining Factors of National Advantage [online]. Available from http://www.themanager.org/Models/diamond.htm. [Accessed 20/04/2003].

Stacey, R , 1993. *Strategic Management and Organisational Dynamics.* 1st ed. Pitman Publishing, London; 113-115.

Steinman MA, Shlipak MG, McPhee SJ, 2002. Of pamphlets and pens : attitudes and practices of medicine house staff towards pharmaceutical industry promotions. *American Journal of Medicine* ; **(7) :** 551-552.

Stryer D, Bero LA, 1996. Characteristics of materials distributed by drug companies : an evaluation of representatives. *J Gen Int Med* ; **(11)** : 575-583

Thompson, A.A. and Strickland, T. 2001. *Crafting and Executing Strategy: Text and Readings.* 12th ed. Singapore: McGraw-Hill.

Tong KL, Lien CY, 1995. Do pharmaceutical representatives misuse drug samples? *Can Fam Physician* ; **41** : 1363-1366.

Wilkes MS, Doblin BH, Shapiro MF, 2000. Pharmaceutical ads in leading medical journals: experts assessments. *Canadian Family Physician* ; **102:** 1245-1246.

Zuckerman A, 2000. Healthcare Financial Management: Leveraging Strategic Planning for Improved Financial Performance. Available from: http://www.quickmba.com. Accessed: 20/04/03.

ABBREVIATIONS

AMA	American Medical Association
APA	American Psychiatric Association
ARR	Absolute Risk Reduction
BHF	Board of Health Funders
CME	Continuing Medical Education
CPD	Continuing Professional Development
CNS	Central Nervous System
DOH	Department of Health
EBM	Evidence Based Medicine
EDL	Essential Drugs List
HPCSA	Health Professionals Council of South Africa
IPA	Independent Practitioners Association
MCC	Medicines Control Council
MMAP	Maximum Medical Aid Price
MNC	Multinational Corporation/Company
MRSCA	Medicines and Related Substances Control Amendment Bill
NAPM	National Association for Pharmaceutical Manufacturers
NDP	National Drug Policy
NICE	National Institute for Clinical Experience
NMP	National Medical Plan
NNT	Number to Treat
NSAID	Non-steroidal Anti-inflammatories
PMA	Pharmaceutical Manufacturer's Association
R&D	Research and Development
RRR	Relative Risk Reduction
SA	South Africa
SAMA	South African Medical Association
SASOP	South African Society of Psychiatrists
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
US	United States
WHO	World Health Organization
WTO	World Trade Organisation

GLOSSARY

Exhaustion of Rights

The term "exhaustion of rights," describes the termination of patent rights following the legal sale of a good. This is sometimes called the "first sale doctrine." A patent grants a party a monopoly on the sale of a good. Under the first sale doctrine, once a good is sold by the patent owner, the purchaser is free to resell the good, even if the resale of the good competes against sales offered by the patent owners.

Parallel Imports

Parallel imports refers to the situation where the patent owner holds patents in more than one country, and a third party purchases goods in one country and imports the goods into another country without authorization from the patent owner. Patent owners typically sell the same goods at different prices in different countries. The pharmaceutical industry has lobbied against parallel imports because they want to use price discrimination based upon the degree of competition in each market. Countries that permit parallel imports benefit from opportunities to acquire pharmaceuticals at the lowest international prices.

The Food and Drug Administration (FDA)

The FDA regulates the sale of pharmaceuticals. For a new drug, a firm must submit data to the FDA which is used to evaluate the safety and efficacy of the drug. If a drug is protected by a patent, or by exclusive marketing protections under the Orphan Drug Act, the FDA will not grant another company marketing approval. If the drug is not protected by patent, and not protected by the exclusivity marketing provisions of the Orphan Drug Act, another firm can seek marketing approval for the same drug. However, for five years, the FDA requires the any new firms present their own data which proves the safety and efficacy of the drug, even though the FDA has already determined the drug to be safe and effective. After 5 years from when the drug was approved for marketing, and after any patents or Orphan Drug marketing exclusivity expire, a firm can obtain marketing approval for a drug by showing that a product is biologically equivalent to the approved drug.

APPENDIX ONE: MEDICINES AND RELATED SUBSTANCES AMENDMENT ACT, 2002, ACT No.59, 2002

"To provide that a member of the council or committee shall declare his or her commercial interest related to the pharmaceutical or health care industry; to provide that the appointment of members of the executive committee is subject to the approval of the Minister; to provide for the control of medicines and scheduled substances and medical devices; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to provide that labels be approved by the council; to prohibit sampling and bonusing of medicines; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers and distributors; to provide for the generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to make new provisions for appeals against decisions of the Director-General or the council; to provide that the council may make regulations; to provide for the rationalization of certain laws relating to medicines and related substances that have remained in force in various territories on the national territory of the Republic by virtue of item 2 of Schedule 6 to the Constitution of the Republic of South Africa, 1996; and to provide for matters connected herewith."

APPENDIX TWO : PEST ANALYSIS

PEST Analysis

POLITICAL	ECONOMIC
▪ Political stability ▪ Risk of military invasion ▪ Legal framework ▪ Intellectual property protection ▪ Trade regulations & tariffs ▪ Favoured trading partners ▪ Anti-trust laws ▪ Pricing regulations ▪ Taxation ▪ Wage legislation ▪ Work week ▪ Mandatory employee benefits ▪ Industrial safety regulations ▪ Product labelling requirements	▪ Type of economic system ▪ Government intervention in the free market ▪ Comparative advantages of host country ▪ Exchange rates & stability of host country currency ▪ Efficiency of financial markets ▪ Infrastructure quality ▪ Skill level of workforce ▪ Labour costs ▪ Business cycle stage ▪ Economic growth rate ▪ Discretionary income ▪ Unemployment rate ▪ Inflation rate ▪ Interest rates
SOCIAL	**TECHNOLOGICAL**
▪ Demographics ▪ Class structure ▪ Education ▪ Culture ▪ Entrepreneurial spirit ▪ Attitudes ▪ Leisure interests	▪ Recent developments ▪ Technology's impact on product offering ▪ Impact on cost structure ▪ Impact on value chain structure ▪ Rate of technological diffusion

Source: Internet 9

APPENDIX THREE : SWOT ANALYSIS

SWOT ANALYSIS	KEY ISSUES IN THE ENVIRONMENT					
STRENGTHS/ WEAKNESSES	Politics/ Legislation	Link between poverty & health	New technology (medical)	Public Expect- Ation	Demo- Graphic Trends	Comp- etetive Market
Main Strengths						
Innovation	+	+	+	++	+	++
Good GP links	+	++	+	+	+	+
Employees	+	+	+	+	0	+
Collaboration	+	++	0	+	+	-
Main Weaknesses						
No outcome Measures	-	- -	-	-	-	-
IT	-	-	-	-	-	-
No growth	+	-	-	-	-	+
Provider agenda	0	0	--	--	--	++
Govt. decides Role	-	0	0	-	0	--